CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on November 17, 2005.

John S. Nagy, Reg. No. 30,664

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/693,577
Applicant	:	Lilip Lau, Bill Hartigan
Filed	:	October 23, 2003
Art Unit	:	3736
Examiner	:	Samuel G. Gilbert
Title		SELF-SIZING CARDIAC HARNESS FOR TREATING CONGESTIVE HEART FAILURE
Docket No.:	:	PARCR 65971
Customer No.	:	24201

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Dear Sir:

I, DARRELL H. OGI, DECLARE AS FOLLOWS:

1. I am an employee of Paracor Medical, Inc., the Assignee of the present application. I previously worked for Paracor Surgical, Inc., the predecessor of Paracor Medical, Inc., and presently I am Director of Clinical Engineering.

2. I have first-hand knowledge of the facts set forth herein. I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

3. Through the instructions of the co-inventors of the present application, Lilip Lau and Bill Hartigan, and with their guidance, I worked on the development of a cardiac harness from a time just before October 8, 1999.

4. Attached hereto as Exhibit A are laboratory notebook pages, in my handwriting, as evidence of the development work that I was instructed to do with respect to the cardiac harness prior to October 8, 1999. The dates have been redacted, however, my signature and the signature of a witness appear on some of the notebook pages. The notebook pages are consecutively numbered and show continuous development work.

5. Attached hereto as Exhibit B are laboratory notebook pages, in my handwriting, as evidence of the development work that I was instructed to do on the cardiac harness after October 8, 1999. The notebook pages are consecutively numbered and show continuous development work. Upon information and belief, I worked on almost a daily basis on the development of the cardiac harness, and periodically made entries in my laboratory notebook relating to the work I had completed.

6. All of the development work that I was instructed to do was conducted in the United States at Palo Alto, California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and I acknowledge that any willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and may jeopardize the validity of the application or patent issuing thereon.

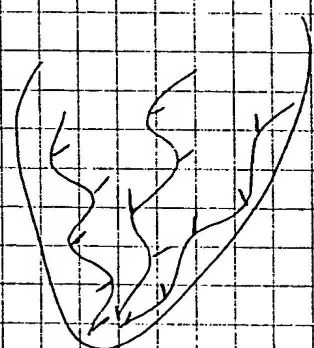
Date: 11/14/05

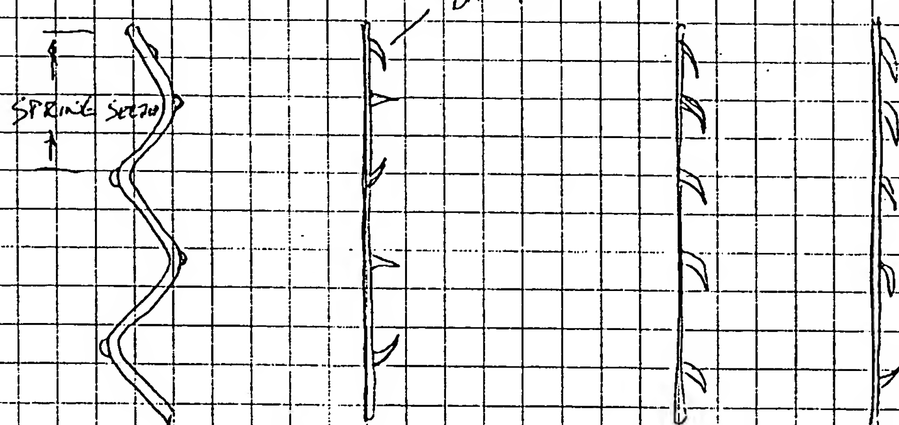
Darrell H. Ogi

106308.1

METAL STRIPS WITH ANCHORS & SPRING COMPONENT

METHOD OF STRAIN RELIEF AND ENHANCED CONTRACTILITY OF MUSCLE TISSUE. INSTEAD OF A BASKET, RUN STRIPS OF SPRINGS ALONG THE INSIDE OF THE VENTRICLE TO REDUCE DISTENSION OF THE WALL AND ASSIST CONTRACTILITY

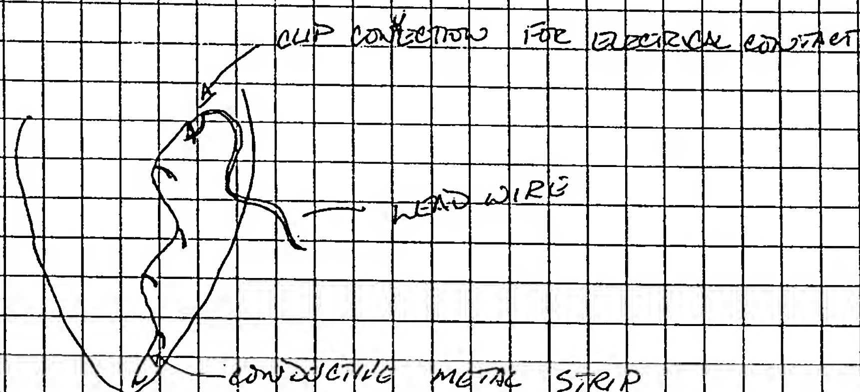




READ & UNDERSTOOD

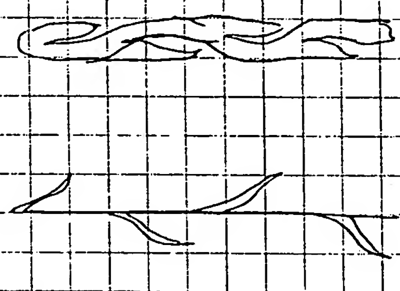
METAL STRIPS AS AN ELECTRICAL CONDUCTOR

THE METAL STRIPS USED TO STRAIN RELIEVE THE LEFT VENTRICAL WOULD MOST LIKELY BE MADE OF STAINLESS STEEL, OR NICKEL TITANIUM, BOTH OF WHICH CONDUCT ELECTRICAL CURRENT. POTENTIALLY USE THE METAL STRIPS AND ANCHORS AS AN ELECTRODE TO PACE THE LEFT VENTRICLE. CAN PACE IN CONJUNCTION WITH RIGHT VENTRICULAR, OR RT DUAL CHAMBER PACING. ELECTRICAL CONTACT MAY BE MADE THROUGH THE MYOCARDIUM, OR THROUGH THE SEPTUM.



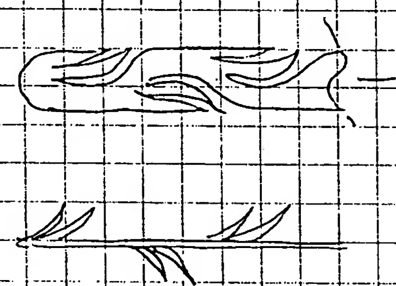
READ + UNDERSTOOD

SHEET METAL ANCHORS

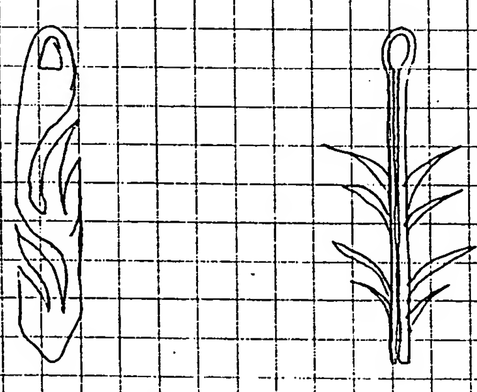


STAINLESS STEEL
OR Ni Ti

LOW PROFILE, EASY
INSERTION INTO TISSUE,
BUT REASONABLE ANCHORING
FORCE



MORE BARBS TO
CREATE MORE SURFACE
AREA

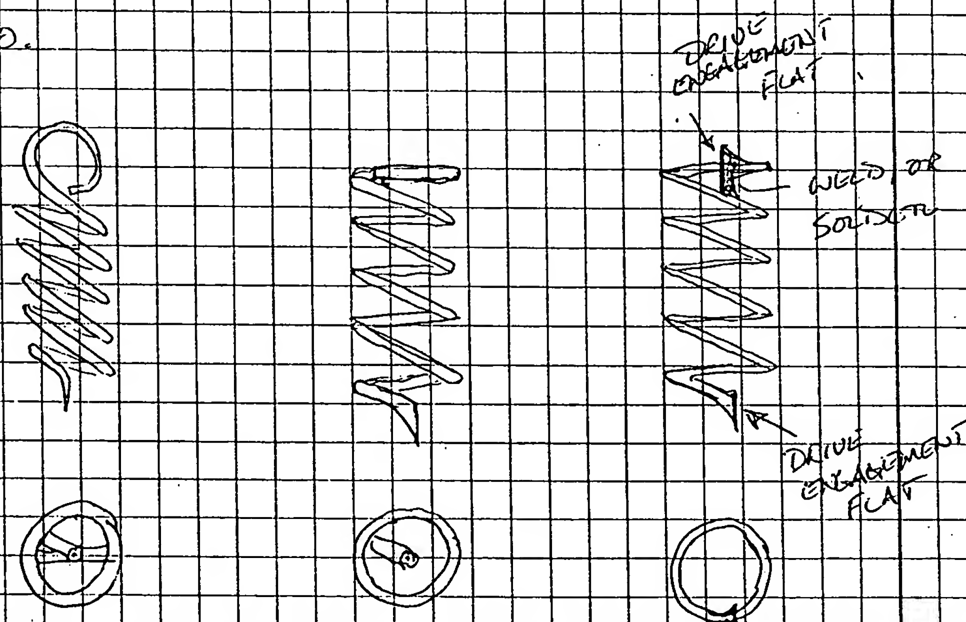


DOUBLE LAYERED
SHEET METAL STRIP
WITH BARBS IN OPPOSING
DIRECTION. BASE
STRIP MAY BE
TWISTED TO SPREAD
BARBS CIRCUMFRENCIALLY

READ + UNDERSTOOD

COIL SPRINGS AS ANCHORS

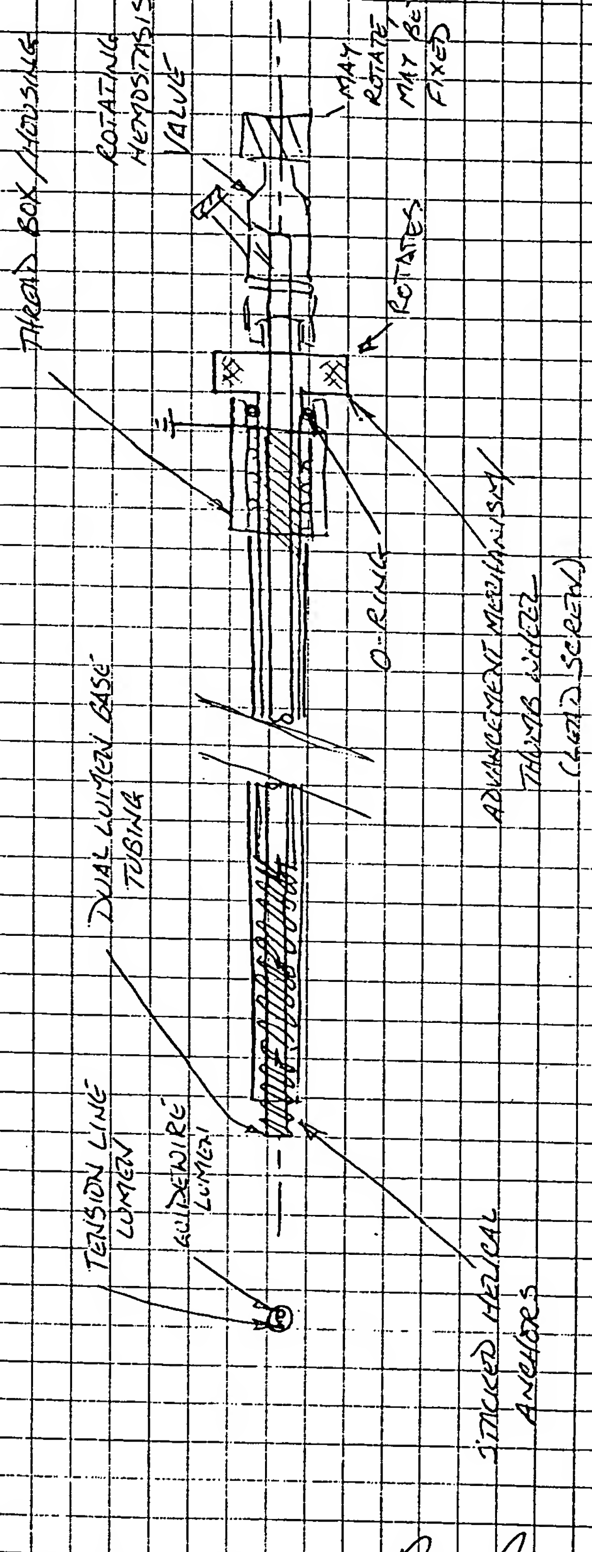
METAL COILS WITH A CONSTANT PITCH MAY TAKE MINIMAL FORCE TO INSERT INTO TISSUE THAN SHEET METAL BARBS. COILS MAY HAVE A SINGLE ENTRY WOUND AND TEAR LESS TISSUE IF "SCREWED" INTO THE TISSUE LIKE A CORKSCREW RATHER THAN TEARING TISSUE LIKE A BARB MAY DO.



[signature]

READ + UNDERSTOOD [signature]

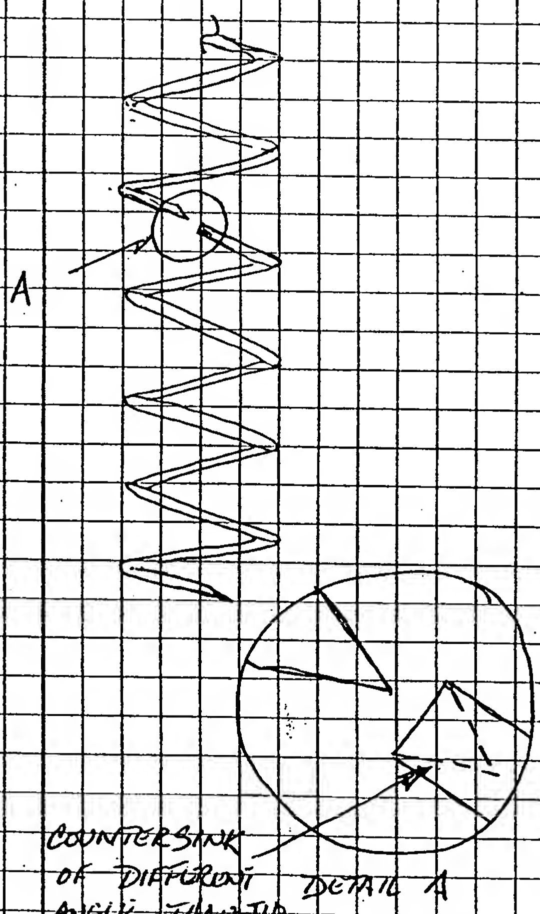
DELIVERY CATHETER/DRIVE MECHANISM

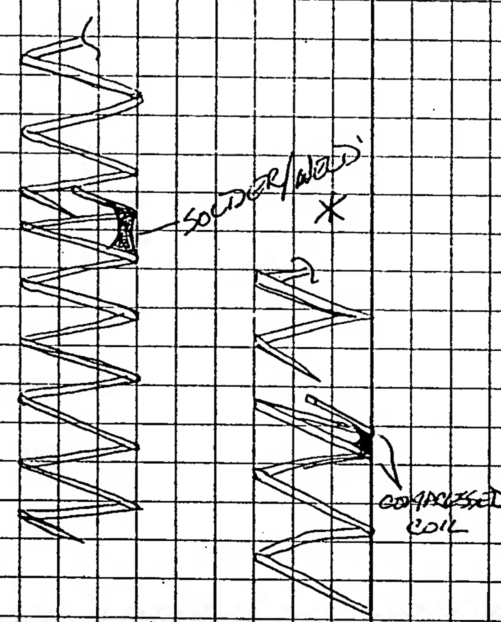


READ + UNDERSTOOD Diana Carter

COIL SPRING TERMINATIONS

A METHOD WILL BE NEEDED FOR INDIVIDUAL ANCHOR SPRINGS/COILS TO BE ABLE TO ENGAGE WITH ONE ANOTHER SUCH THAT TORQUE MAY BE TRANSMITTED FROM ONE COIL TO ANOTHER. WITH SUFFICIENT ENGAGEMENT, MULTIPLE COILS CAN BE LINED UP AND DRIVEN FROM THE PROXIMAL END.



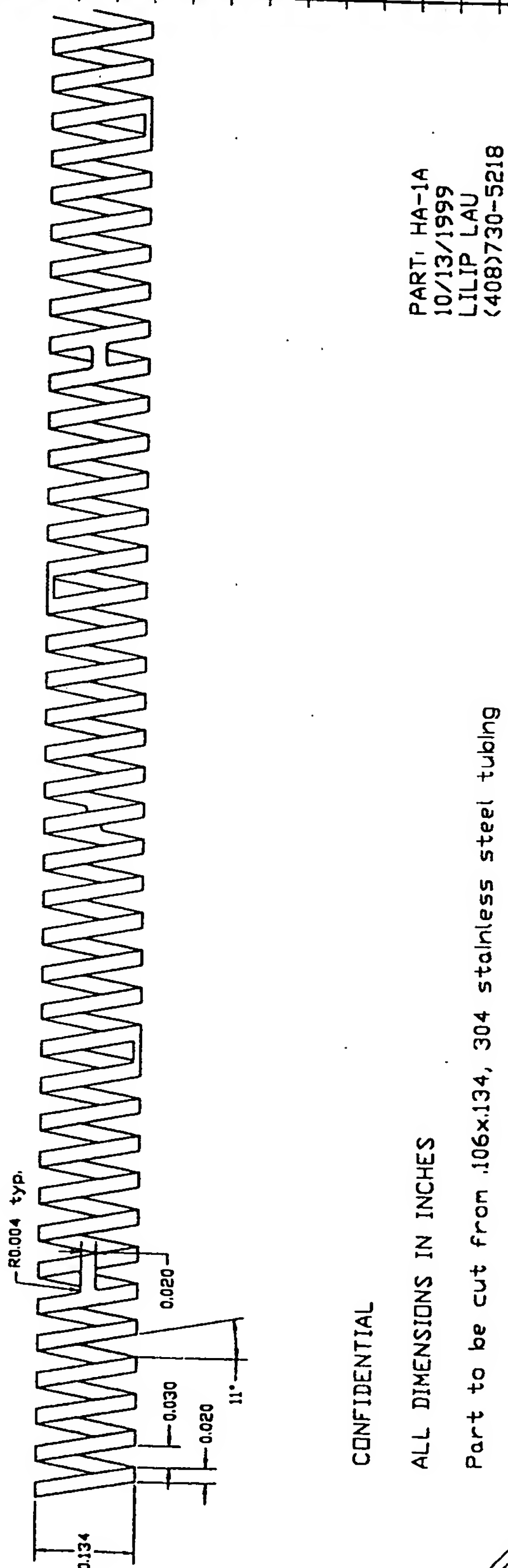


* SOLDER/WELDED COIL MAY BE COMPRESSED TO REDUCE WICKING EFFECT DUE TO SURFACE TENSION

Daniel [signature] 10-13-99

READ & UNDERSTOOD [signature] 10/17/99

PATTERN TO LASER CUT COILS FROM TUBING



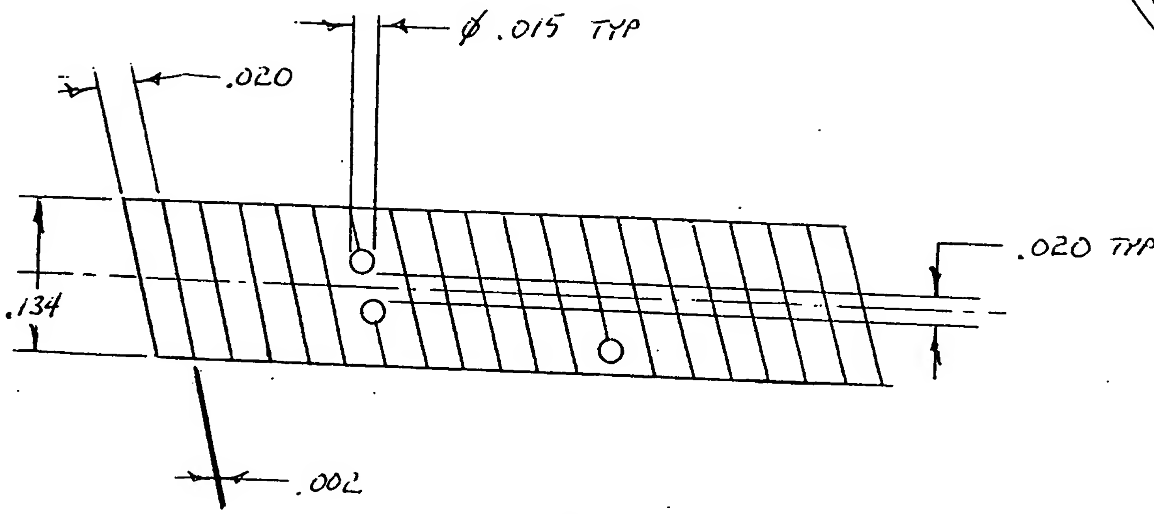
DHO 10-19-99

10-19-99

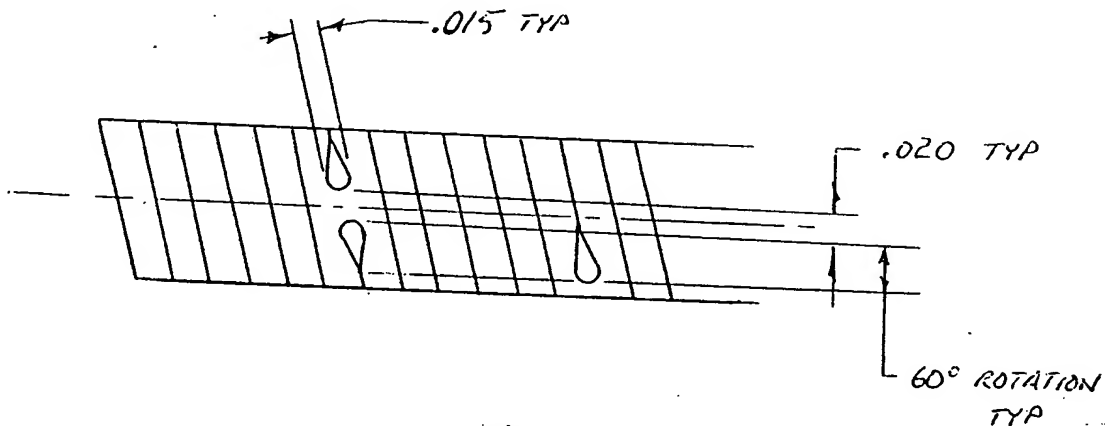
READ & UNDERSTOOD: 10/30/99

8

REVISED LASER CUT PATTERN



OPTION A



OPTION B

CONFIDENTIAL

REVISED PATTERN FOR PART HA-1A (10-13-99)

PATTERN REPEATS EVERY 6 1/4 REVOLUTIONS RH THREAD

ALL DIMENSIONS IN INCHES UNLESS OTHERWISE NOTED

PART TO BE CUT FROM .106 X .134 ø, 304 STAINLESS STEEL TUBING

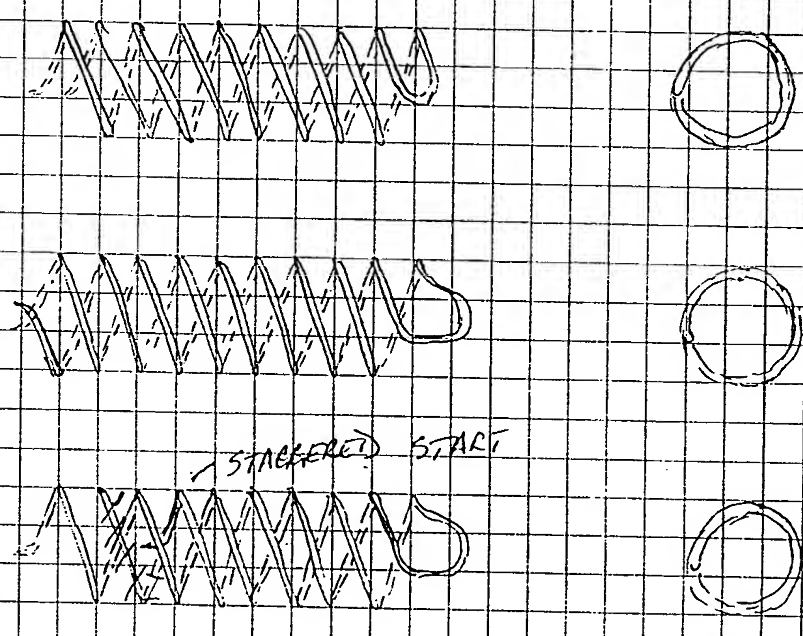
DHC 10-19-99

REVISED PATTERN TO ELIMINATE DOUBLE PASS OF LASER TO CUT THE HELICAL PATTERN. PARTS MUST BE STRETCHED TO THE DESIRED PITCH ANGLE.

READ + UNDERSTOOD: [signature] 10/30/99 [signature] 10-19-99

TETHER LINE CLOSING LOOP FOR ANCHORS

THE END LOOP OF THE ANCHOR MUST BE SMOOTH, WITH NO SHARP TRANSITIONS SUCH THAT THE TETHER LINE CAN MOVE FREELY THROUGH THE CLOSING LOOP WITHOUT FRAYING, CUTTING OR ABRADING. A WELD, SOLDER JOINT, OR PINCHED COIL COULD HAVE A SHARP EDGE THAT COULD DAMAGE THE TETHER LINE WITH MOVEMENT. ONE METHOD WOULD BE TO USE A DUAL HELIX (RECOMMENDED BY LILIP LAU) WITH A CONTINUOUS PIECE OF WIRE LEAVING A SMOOTH LOOP.



STAGGERED START MAYBE USED TO HELP ASSURE PROPER ENGAGEMENT OF TETHER LINE

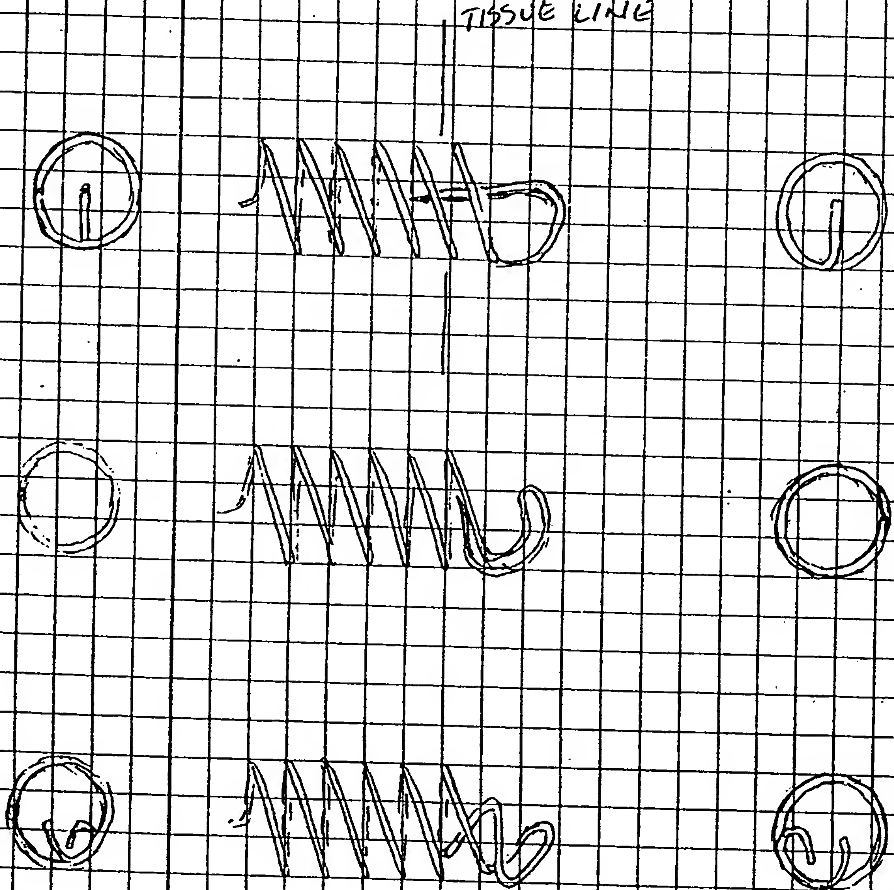
10-26-99

READ & UNDERSTOOD: 10/30/99

10-19-99

TETHER LINE CLOSING LOOP

THE CLOSING LOOP END COULD RUN BACK DOWN THE MIDDLE (CENTERLINE) OF THE COILED ANCHOR TO ANCHOR THE END INTO ENDO, OR EPICARDIUM AND ENTRAP THE TETHER LINE WITHOUT ADDING FRICTION TO THE LINE.

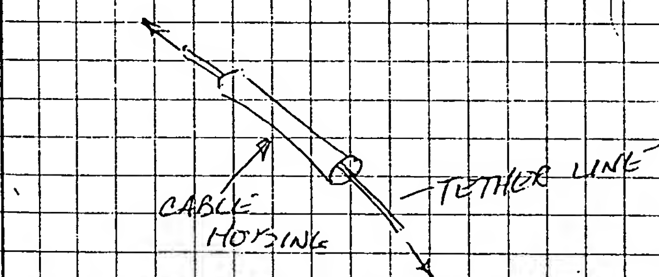


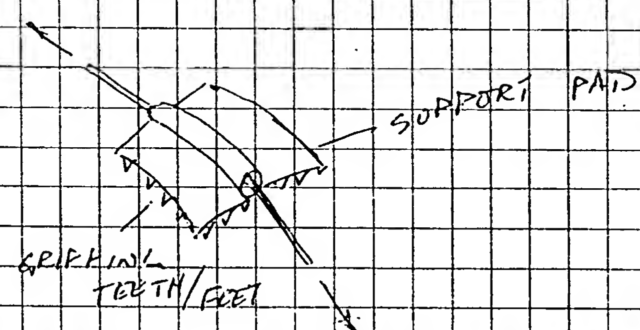
Daniel [signature] 10-26-99

READ + UNDERSTOOD: [signature] 10/31/99

TETHERLINE CABLE HOUSING/PAD

FOR THE EPICARDIAL APPLICATION OF THE TETHER LINE SYSTEM, THE TETHER LINE COULD CONCEIVABLY CUT THROUGH THE EPICARDIAL AND MYOCARDIAL TISSUE WITH TENSION AND MOVEMENT (LIKE A CABLE SAW). A CABLE HOUSING COULD REST DIRECTLY ON THE EPICARDIUM TO DISTRIBUTE THE LOAD AND ISOLATE THE TISSUE FROM AXIAL TETHERLINE MOVEMENT.

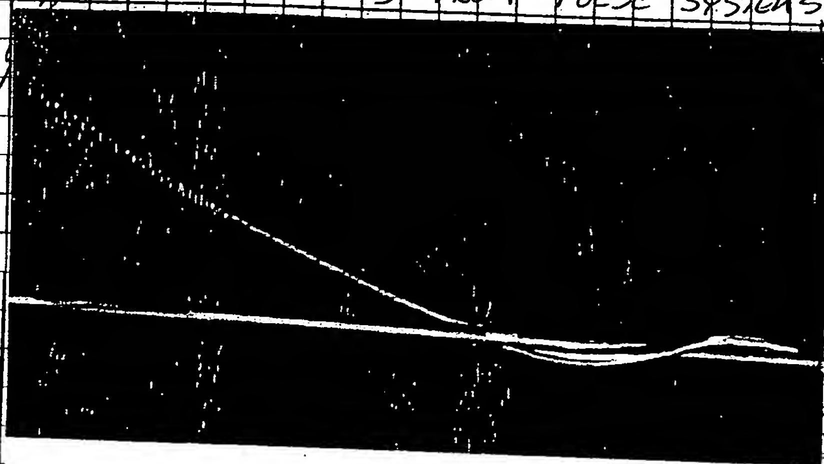


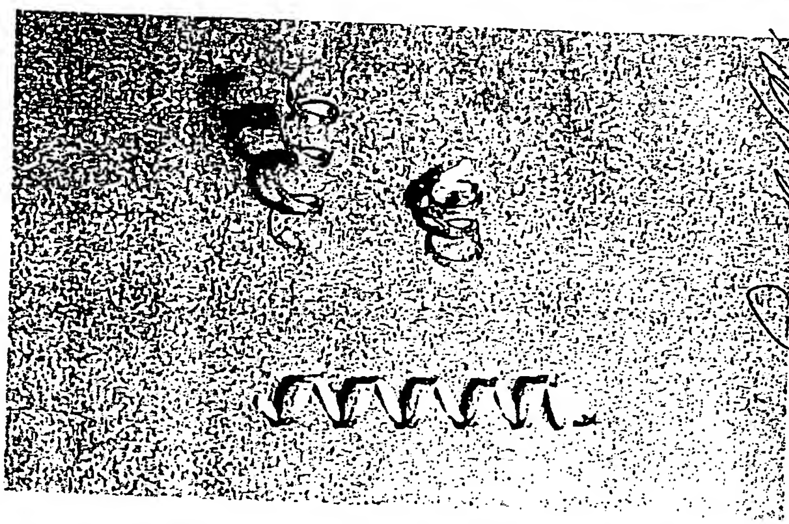


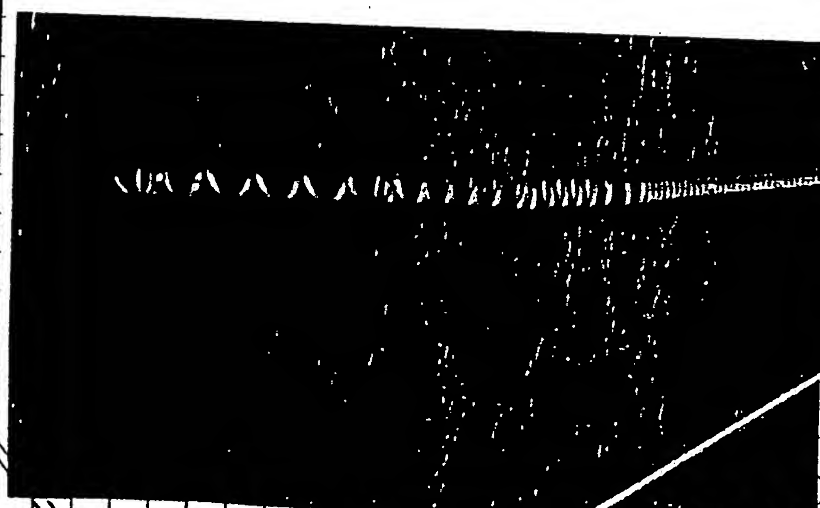
READ + UNDERSTOOD [signature] 10/30/99 [signature] 10-26-99

LASER CUT COILS FROM PULSE SYSTEMS

CUT FROM 304 STAINLESS STEEL MICROTUBING







10-29-99

READ + UNDERSTOOD Diane M. Carter 10/31/99

10-29-99

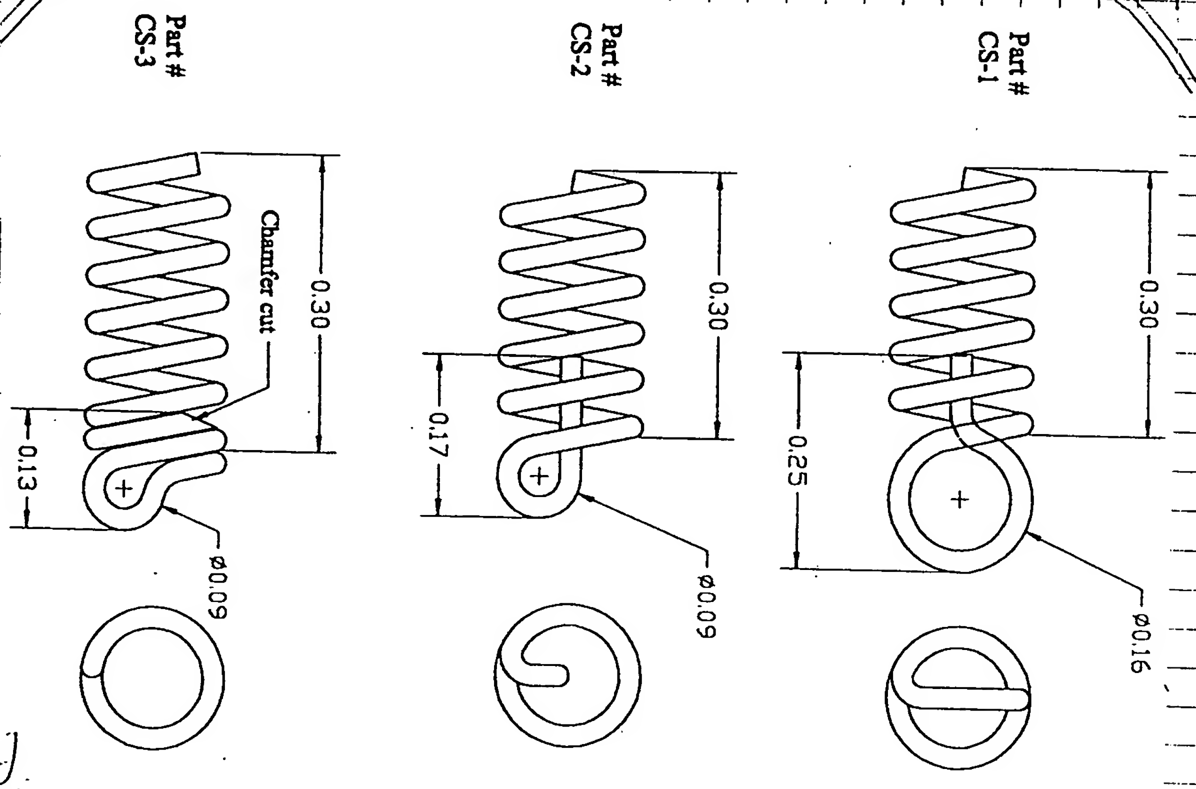
LASER CUT COILS FROM TUBING

THE LASER CUT TUBING FROM PULSE SYSTEMS IS MUCH MORE FLEXIBLE THAN EXPECTED. THE .002" WIDE CUTS IN A HELIX ALLOWS FOR LESS LIMITED COMPRESSION AND EXPANSION OF THE INNER AND OUTER SURFACES RESPECTIVELY WHEN THE TUBING IS BENT. THE SAMPLE COILS WERE ALSO INADVERTENTLY CUT WITH A LEFT HAND HELIX RATHER THAN THE SPECIFIED RIGHT HAND HELIX. IN THE UNEXPANDED STATE, THE COILS HAVE VERY POOR TORQUE TRANSMISSION, BUT WHEN EXPANDED TO A HIGHER PITCH, TORQUE TRANSMISSION IS REASONABLE. THE SHORT ANCHOR COILS EXPAND EASILY AND MAINTAIN THEIR OUTSIDE DIMENSION (DIAMETER) WITH EXPANSION. THE EXPANDED ANCHOR COILS BURROW EASILY INTO SILICONE FOAM AND PORCINE MYOCARDIAL TISSUE. THERE APPEARS TO BE SUFFICIENT HOLDING FORCE IN THE FOAM AND TISSUE (COMPARABLE IF NOT EASIER THAN WIRE COIL ANCHORS).

[signature] 10-29-99

READ & UNDERSTOOD [signature] 10/30/99

ANCHORS WITH TETHER LINE CLOSING LOOP



Confidential
Part Numbers:CS-1, CS-2, CS-3
10/28/99
Paradigm Surgical
D. Ogi (408) 396-8835

Notes:
Material: 316 SS
Wire diameter: 0.023"
Spring diameter: 5/32" 0.156"
Pitch: 20 threads per inch
Thread Direction: Right hand thread
Tolerances: +/-.001 ID and OD dimensions

10-29-99

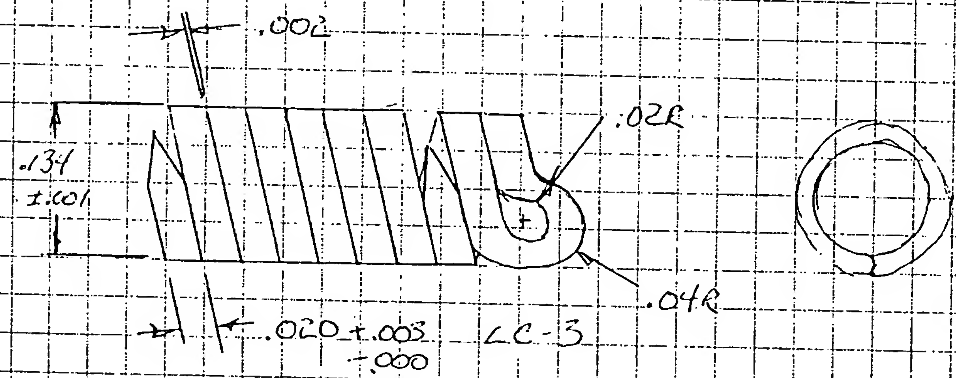
DRAWINGS FAXED TO AMERICAN SPRING BY
BILL HARTIGAN 10-28-99

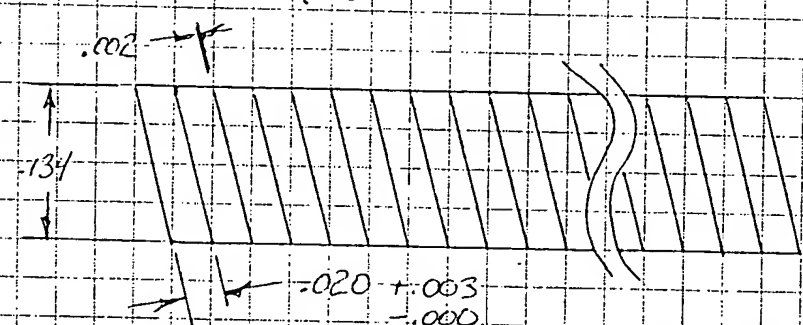
10-29-99 READ + UNDERSTOOD 10/30/99

LASER CUT ANCHOR WITH TETHERING LOOP

AMERICAN SPRING HAD DIFFICULTY IN QUOTING ON PART #'S CS-1, CS-2, CS-3. THE CLOSING LOOP RADIUS IS TOO TIGHT FOR .023" ϕ WIRE. CS-1 WAS THE ONE THAT HAD THE MOST POTENTIAL, BUT WOULD TAKE SPECIAL TOOLING AND 4 TO 6 (SIX) WEEK LEADTIME. A MODIFIED DRAWING OF CS-3 ~~(LC~~ (LC-3) WAS GIVEN TO PULSE SYSTEMS TO LASER CUT FROM A STAINLESS STEEL TUBE.

DHC 12-17-99





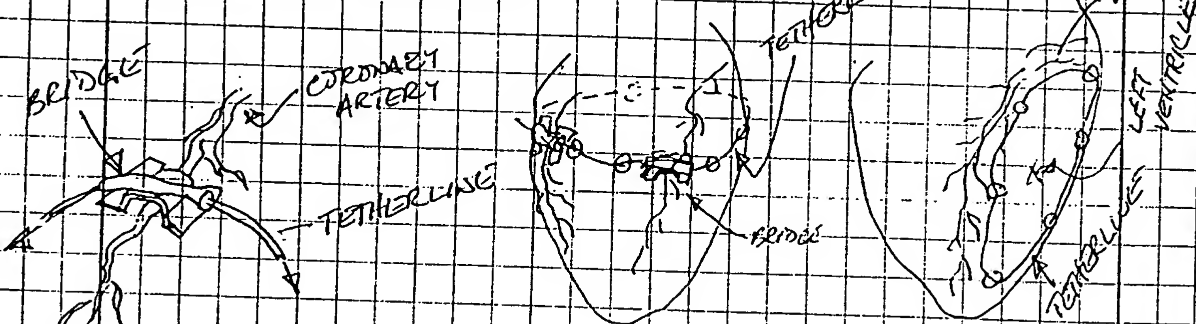
LASER CUT RIGHT HAND COIL

[signature] 11-4-99

READ & UNDERSTOOD: [signature] 12/17/99

AORTIC ASSIST/COMPLETE LOOP

ONE OF THE METHODS OF LEFT VENTRICULAR ASSIST WILL BE TO RUN THE TETHER LINE COMPLETELY AROUND THE HEART RATHER THAN JUST IN STRIPS. SECTIONS OF SIGNIFICANT CORONARY ARTERIES MAY BE BRIDGED BY AN ELEVATED TUBE SO THE CORONARY ARTERY WILL NOT BE PINCHED BY THE TETHER LINE. THE TETHERLINE AND ANCHORS COULD ALSO BE PLACED IN AN ELIPTICAL PATTERN AROUND THE EPICARDIAL SURFACE OF THE LEFT VENTRICLE. THE ADVANTAGE OF THE CONTINUOUS LOOP OF TETHERLINE WILL BE TO REDUCE THE MAXIMUM STRESS ON THE END ANCHOR TERMINATIONS AND DISTRIBUTE THE LOAD MORE EVENLY.

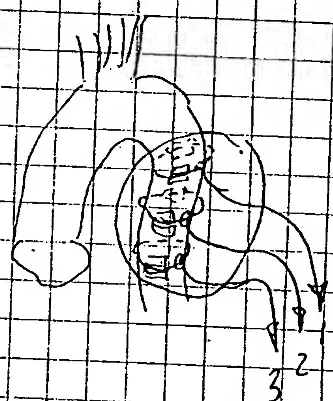


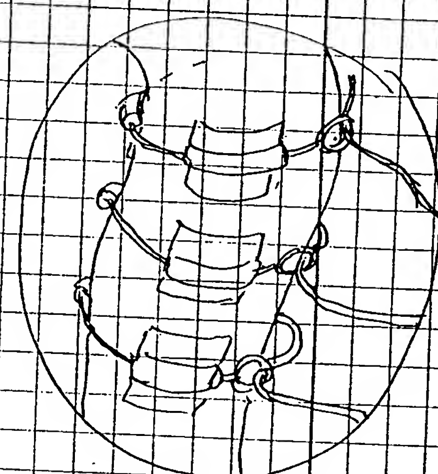
[signature] 11-12-99

READ/UNDERSTOOD [signature] 12/13/99

AORTIC ASSIST

THE CONTINUOUS LOOP TETHERLINE COULD ALSO BE USED AS AN AORTIC ASSIST DEVICE TO RELIEVE LEFT VENTRICULAR WORKLOAD BY SEQUENTIALLY CONTRACTING THE AORTIC WALL TO HELP PUMP BLOOD THROUGH THE AORTA. THE CONTRACTIONS COULD BE TIMED WITH THE CONTRACTIONS OF THE LEFT VENTRICLE TO ENHANCE FLOW RATE.

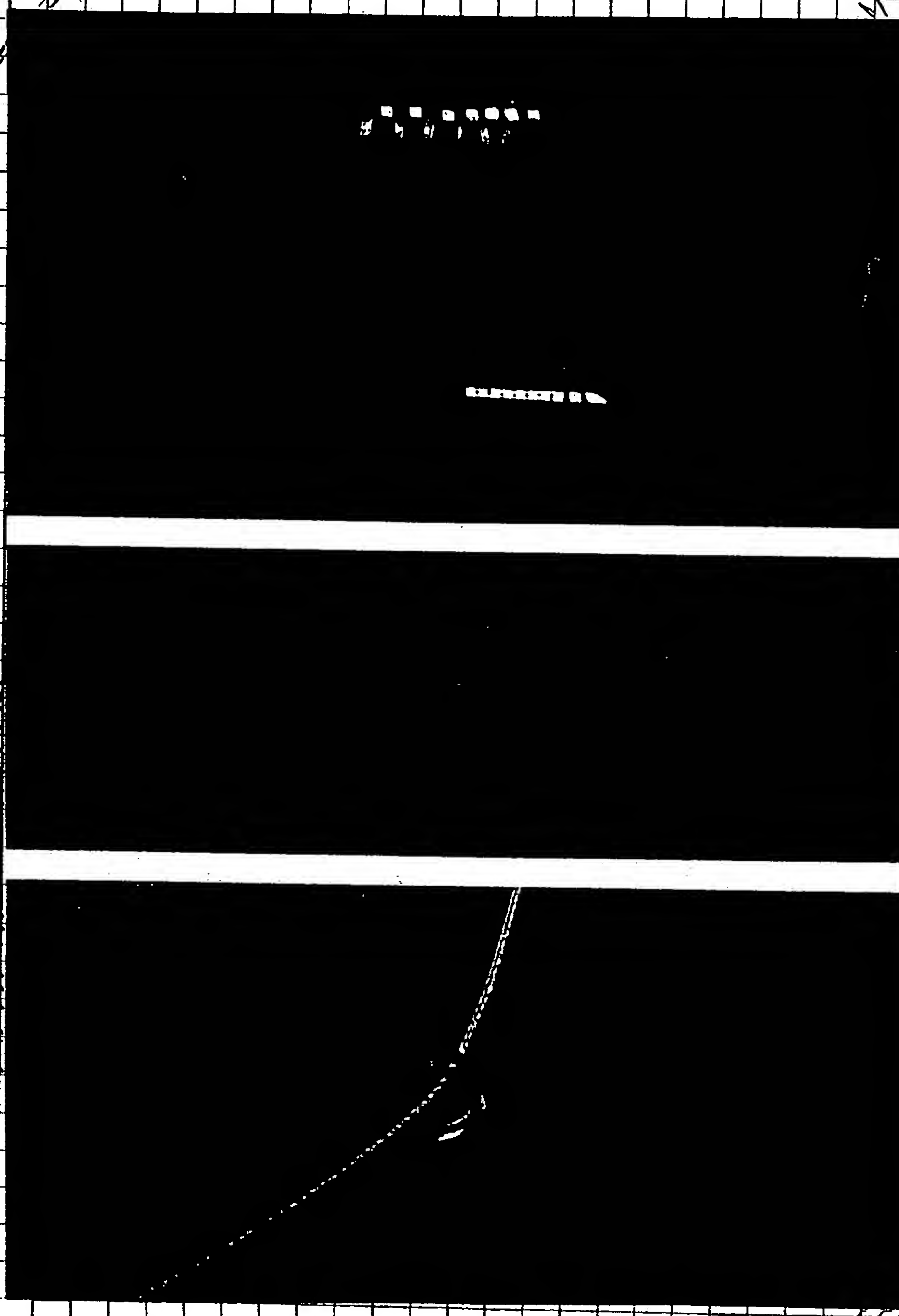




THE SEQUENTIAL "SQUEEZE" WILL HELP ADVANCE BLOOD MUCH LIKE A PERISTALTIC PUMP. PADS COULD BE USED TO DISTRIBUTE THE CONTRACTING LOAD OF THE TETHERLINGS.

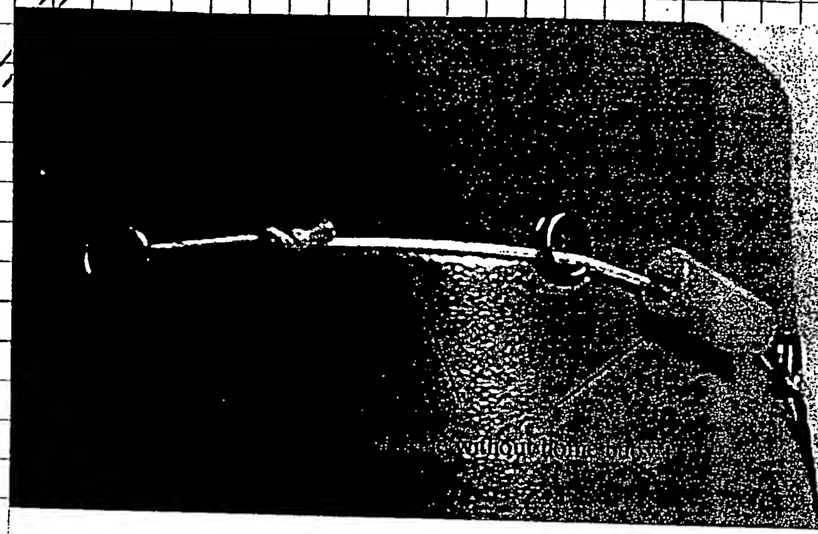
[signature] 11-12-99 READ & UNDERSTOOD [signature] 12/17/99

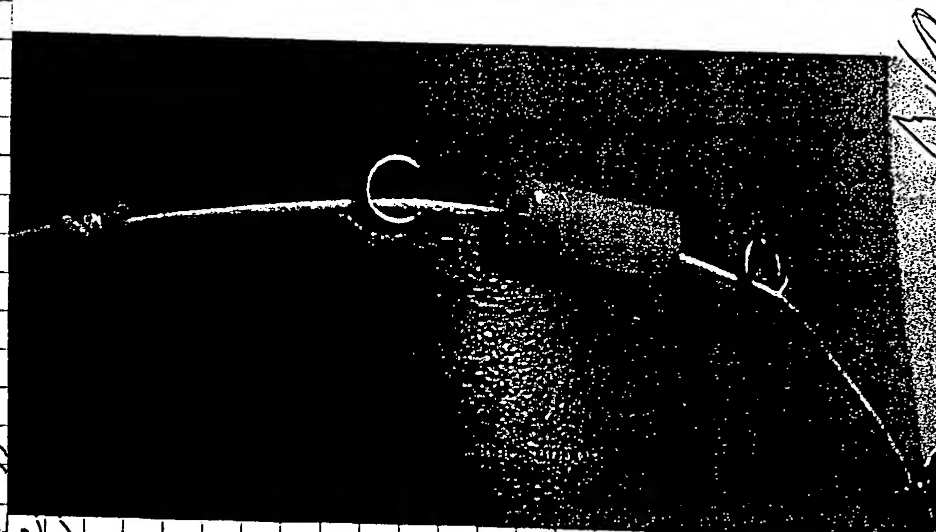
LASER CUT ANCHOR WITH TETHERLINE LOOP



11-17-99 READ & UNDERSTOOD 12/1/99

HOME BUDY STRAIN RELIEF





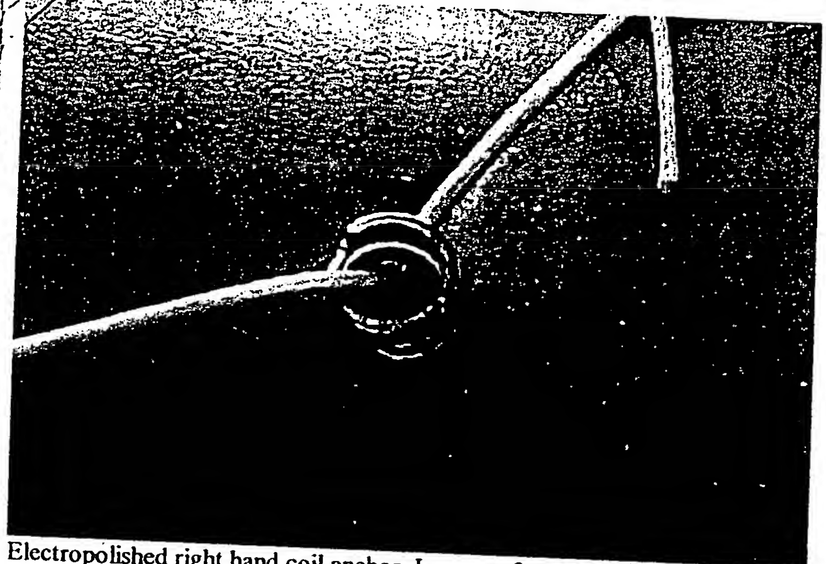
11-17-99

HOME BUDY DISTRIBUTES THE POINT LOADING OF THE TETHERLINE TO REDUCE STRESS ON EPICARDIUM.

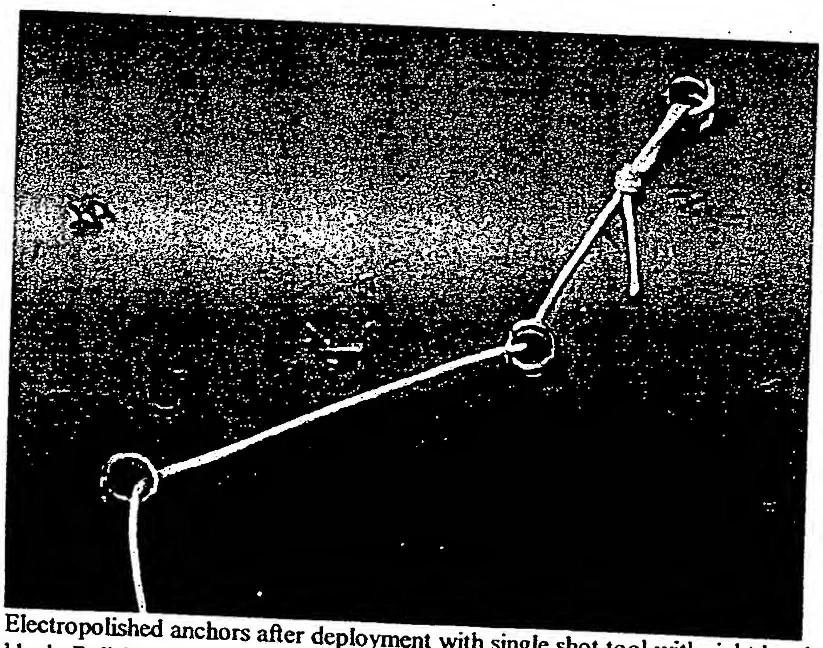
11-17-99

READ & UNDERSTOOD 12/15/99

ELECTROPOLISHING RHT LASERCUT ANCHORS



Electropolished right hand coil anchor. Lasercut from stainless steel tubing, then electropolished.



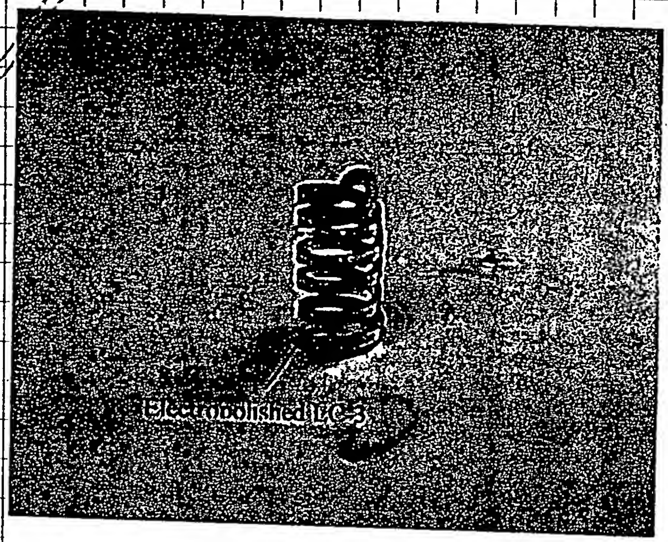
Electropolished anchors after deployment with single shot tool with right hand thread block. Polished parts allow easier movement of tetherline.

11-18-99

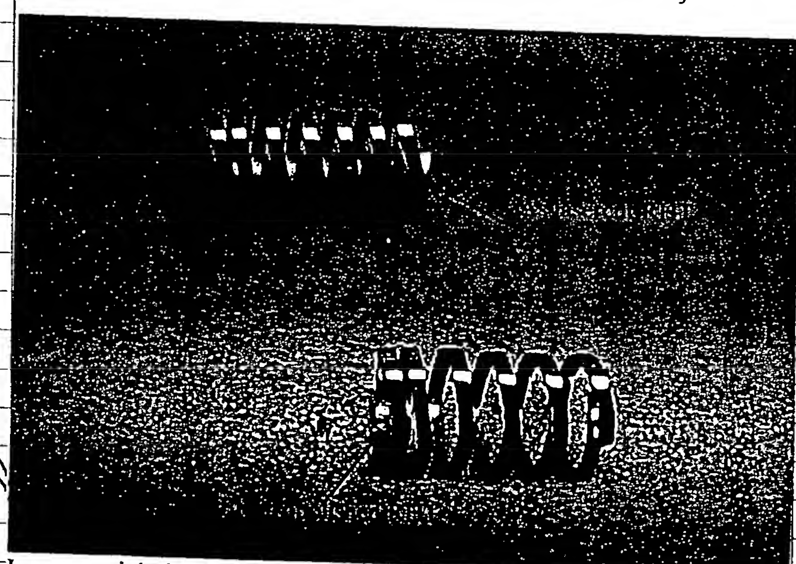
READ, UNDERSTOOD

12/9/99

ELECTROPOLISHED LC-3 ANCHOR



Electropolished at Pullbrite, allows tetherline to slide more freely.



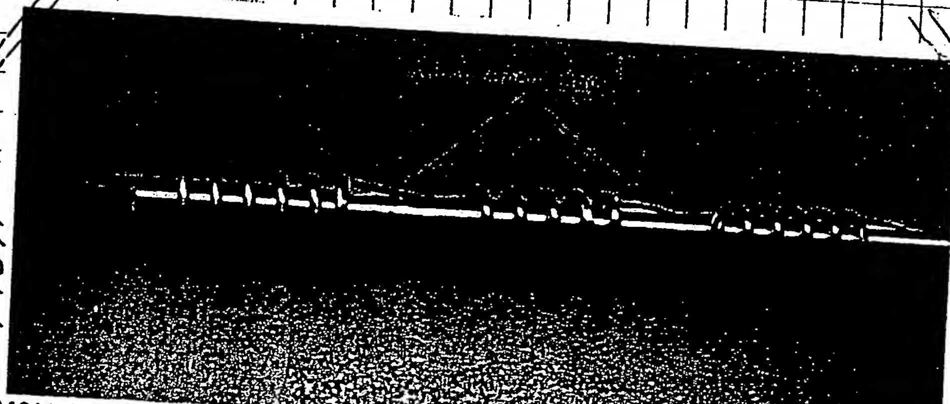
Laser cut right hand coil before and after electropolishing.

11-18-99

11-18-99

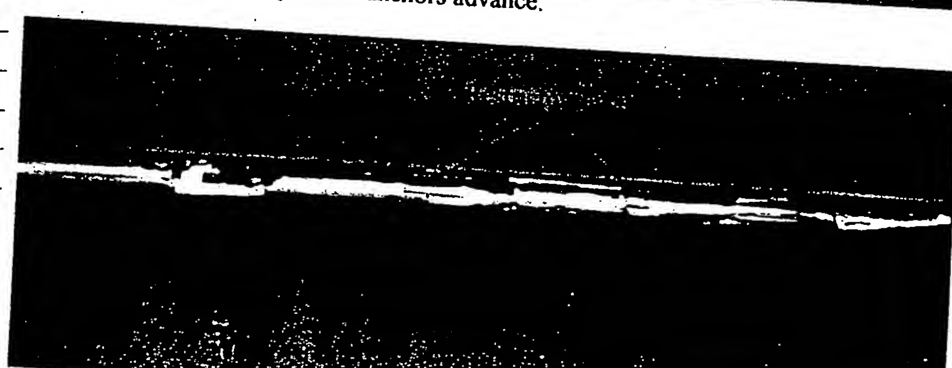
READ & UNDERSTOOD 11/19/99

1911 ANCHOR ADVANCEMENT SYSTEM (SEE LNB #3 PP 4,5)



1911 drive/advance rod with anchors engaged by advancement tangs.

Advancement tangs compress as anchors advance.



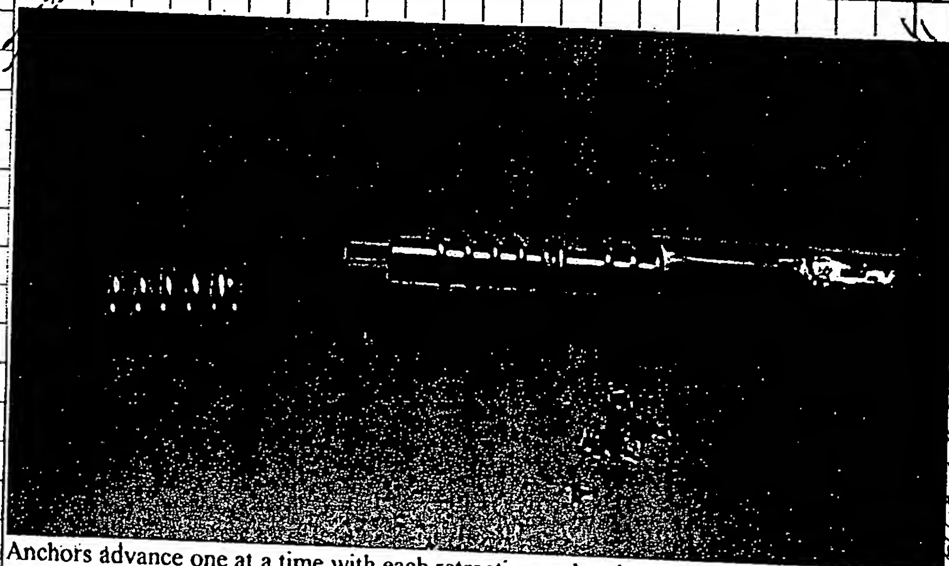
Restrictor tangs deflect up to allow anchor advancement, but drop down to restrict proximal movement of anchors. Tangs reduced from .015" to .007" for more flexibility.

11-18-99

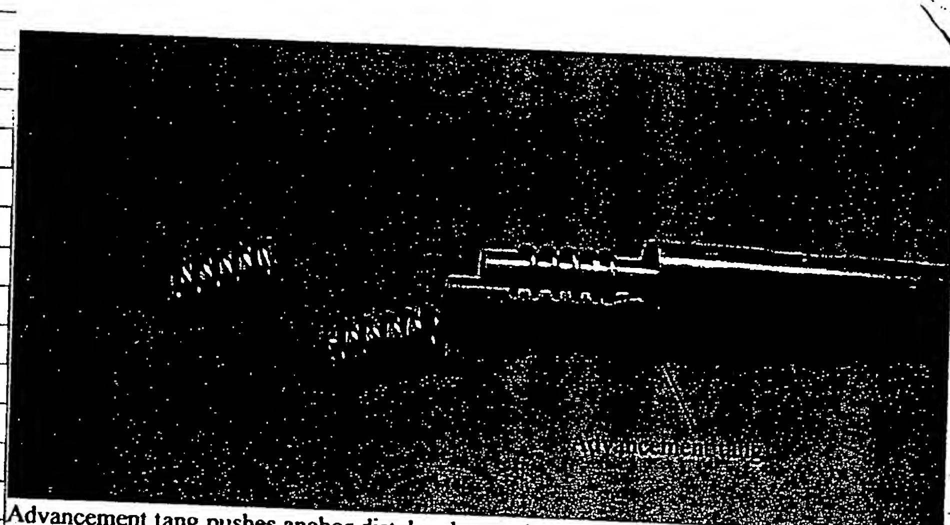
CONCEPT AND DRAWING CAPTURED IN BILL HARTIGAN'S NOTEBOOK.

11-18-99 READ + UNDERSTOOD 12/17/99

1911 CONTINUED



Anchors advance one at a time with each retraction and andvancement of the drive/advancement shaft.



Advancement tang pushes anchor distal and may also drive the anchors helically.

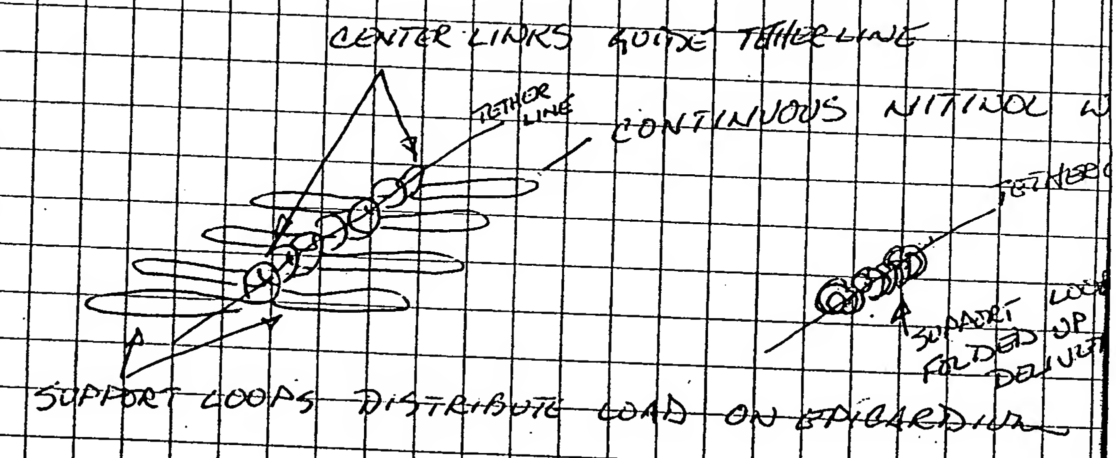
RESTRICTOR TANGS ARE BENT INWARD .010-.020" TO RESTRICT PROXIMAL MOVEMENT OF ANCHORS. ADVANCEMENT TANGS ARE BENT OUTWARD .010"-.030" TO ADVANCE ANCHORS DISTALLY, BUT RETRACT TO ALLOW RETRACTION OF DRIVE ROD TO INDEX THE NEXT ANCHOR.

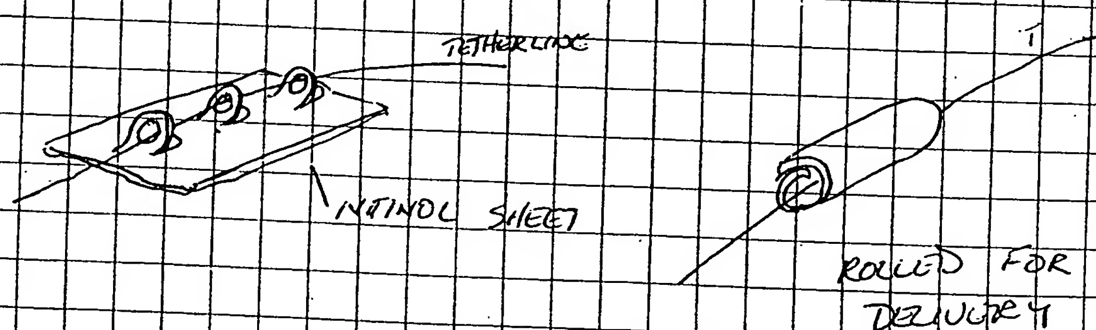
[signature] 11-18-99 READ & UNDERSTOOD [signature] 12/17/99

[signature] 11-18-99

TETHERLINE SUPPORT / STANDOFF

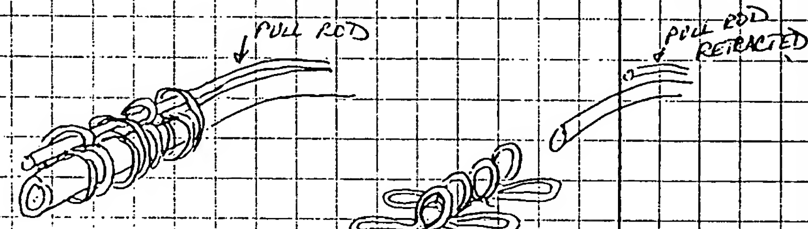
PER PAGE 11 OF THIS NOTEBOOK, A SUPPORT PAD MAY BE NECESSARY TO DISTRIBUTE THE LOAD TO THE EPICARDIUM FROM THE TETHERLINE WHEN TENSIONED. A NITINOL WIRE, OR SHEET CAN BE FORMED INTO A SUPPORT PAD WITH TETHERLINE GUIDES.





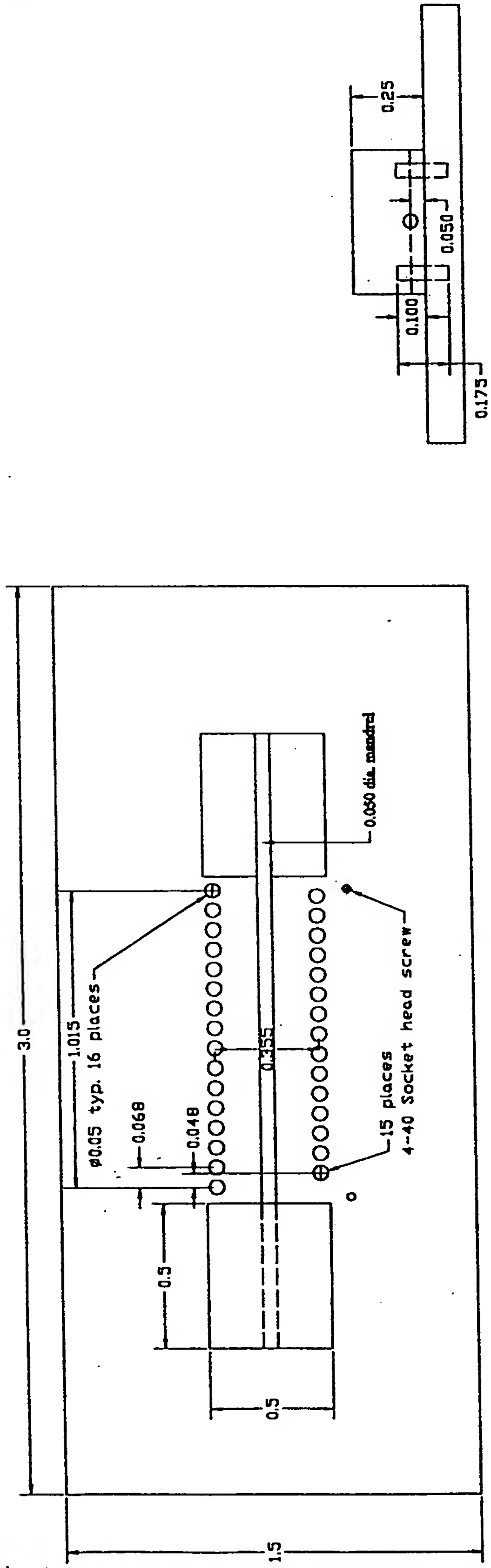
TETHERLINE SUPPORT PAD DELIVERY

THE NITINOL WIRE SUPPORT PAD / STANDOFF CAN BE ROLLED UP AROUND THE CENTRAL TETHERLINE AXIS TO REDUCE THE DELIVERY PROFILE. THIS REDUCED PROFILE CAN THEN BE LOADED INTO A DELIVERY TUBE, CAPTURE DEVICE/SLEEVE, OR HELD COMPRESS WITH A PULL PIN/LINE. THE COMPRESSED STANDOFF CAN BE DELIVERED OVER THE TETHERLINE, BETWEEN THE ANCHORS. RADIOPAQUE MARKERS CAN BE ADDED TO THE SUPPORT PADS FOR VISUALIZATION AND TO AID ORIENTATION. A FOLDED WIRE SUPPORT PAD COULD BE MOUNTED ON A TORQUABLE CATHETER SHAFT WITH A RETRACTABLE PIN TO KEEP ORIENTATION AND DEPLOY THE SUPPORT PAD ON THE EPICARDIAL SURFACE.



[signature] 11-29-99   READ & UNDERSTOOD [signature] 12/15/99

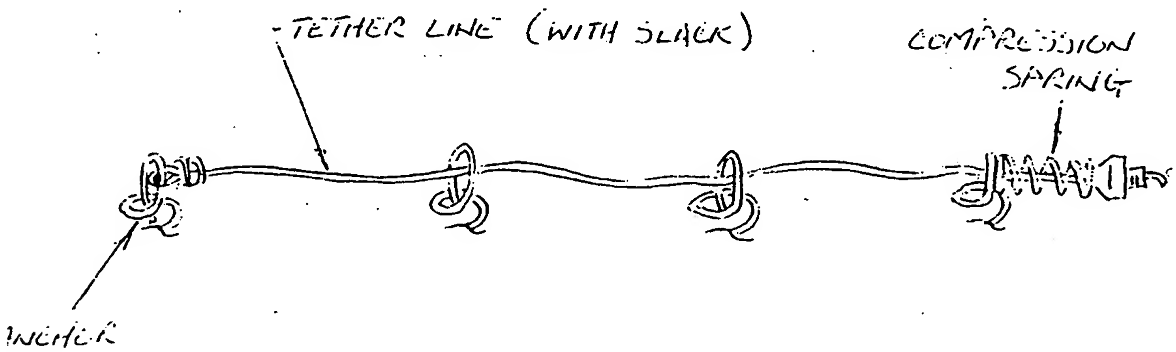
TETHERLINE SUPPORT PAD CURING FIXTURE



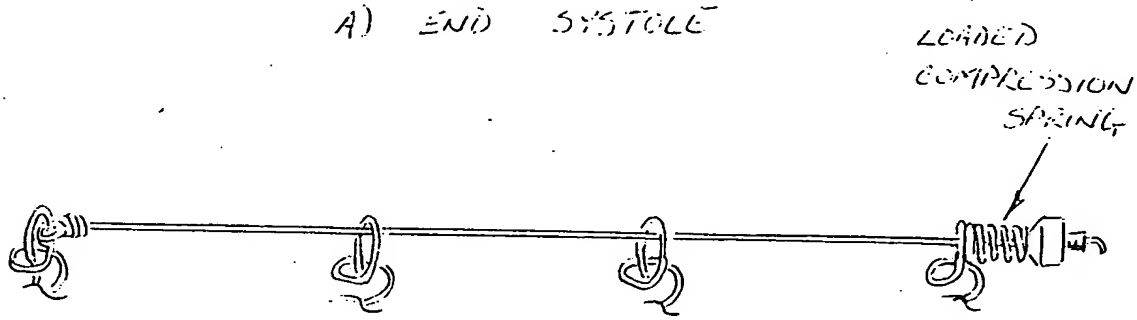
12-2-99

12-2-99 READ + UNDERSTOOD 12/17/99

TETHER LINE WITH COMPRESSION SPRING IN SERIES



A) END SYSTOLE



B) END DIASTOLE

FIGURE 8

TETHER LINE WITH COMPRESSION SPRING IN SERIES.

11-30-99

12-2-99

READ & UNDERSTOOD 12/19/99

ACTIVE LEFT VENTRICULAR ASSIST SCHEMATIC

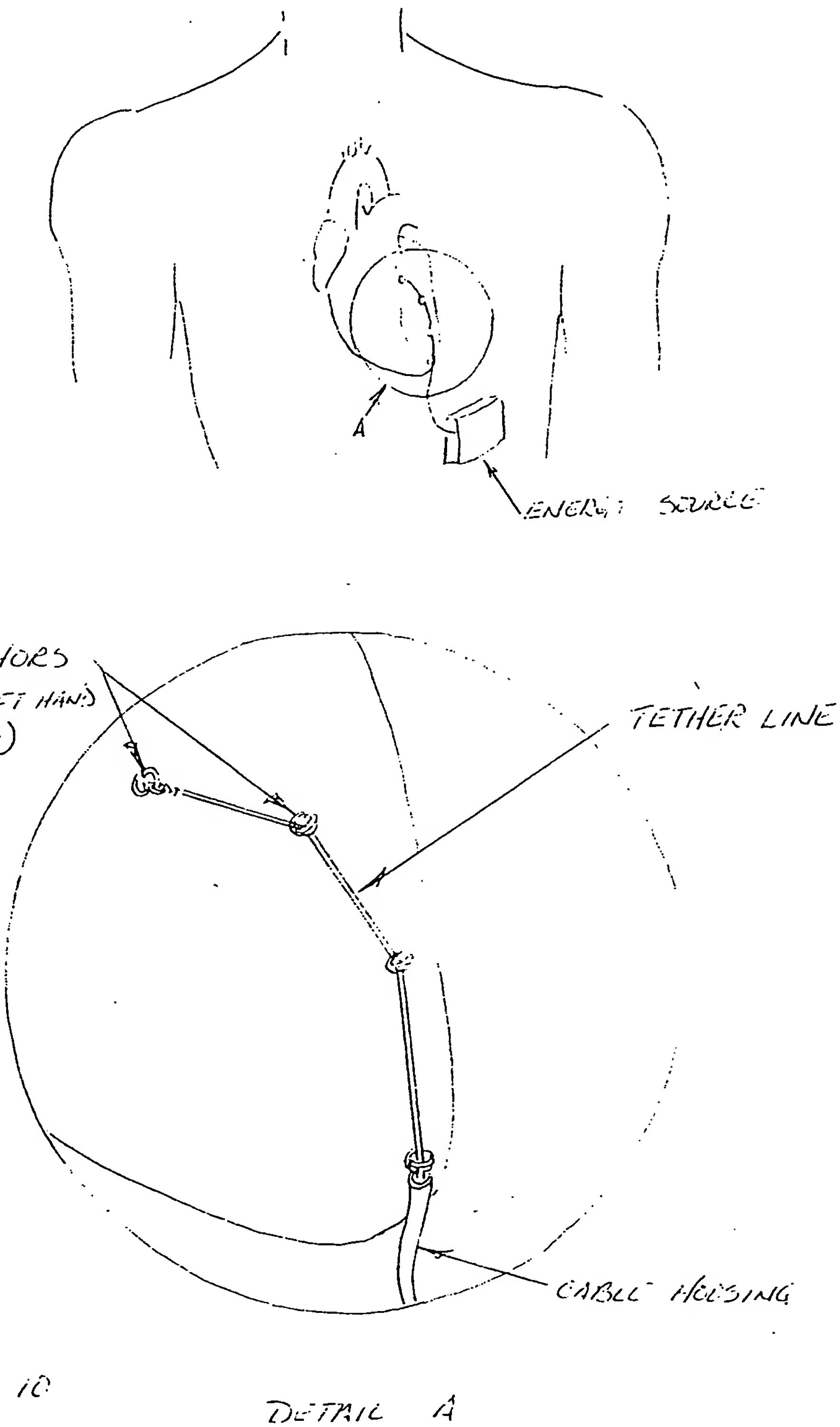
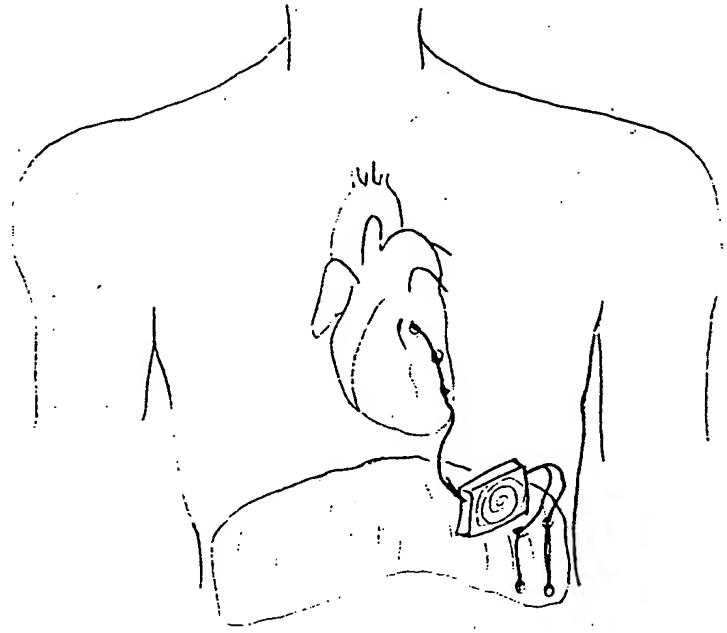


FIGURE 10

12/4/99

READ + UNDERSTOOD 12/9/99

DIAPHRAGM DRIVEN LEFT VENTRICULAR ASSIST.



FIGURES 11 + 12

INPUT FROM DIAPHRAGM TO SPRING MECHANISM, THEN OUTPUT TO CARDIAC HARNESS.

[signature] 12/2/99

READ + UNDERSTOOD [signature] 12/2/99

CHARACTERIZE ANCHOR MOVEMENT FOR GATING

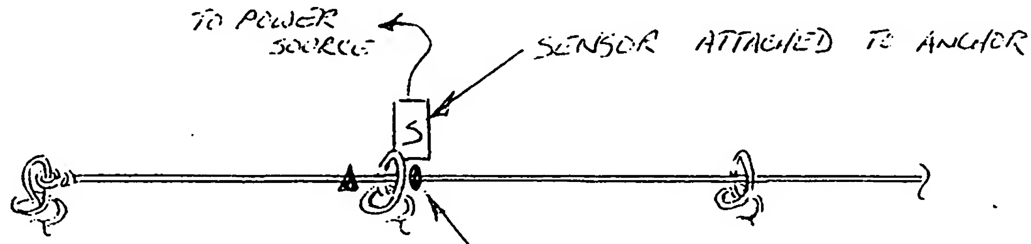


FIGURE 13

GATING / CHARACTERIZING ANCHOR MOVEMENT AT END DIASTOLE.

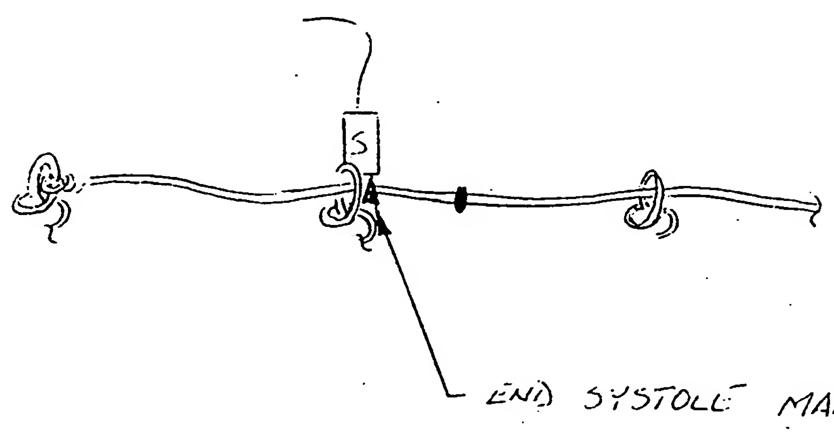


FIGURE 14

GATING / CHARACTERIZING ANCHOR MOVEMENT DURING SYSTOLE.

[signature] 12/2/99

READ + UNDERSTOOD [signature] 12/1/99

ANCHORS WITH PULLEYS

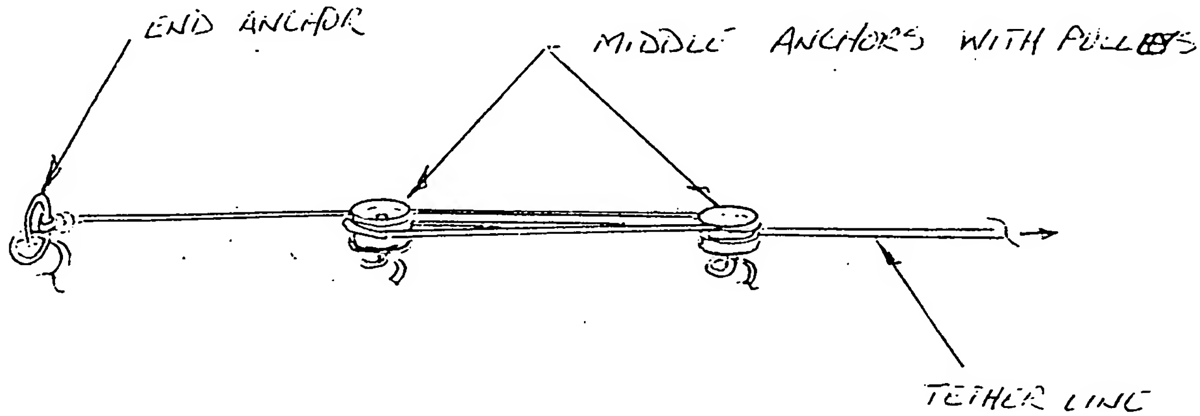


FIGURE 19

ANCHORS WITH PULLEYS ALLOW BACK LOOPING TO DISTRIBUTE LOADING AND MECHANICAL ADVANTAGE.

12/2/99

READ & UNDERSTOOD 12/19/99

ANCHORS USED FOR PACING OR SENSING

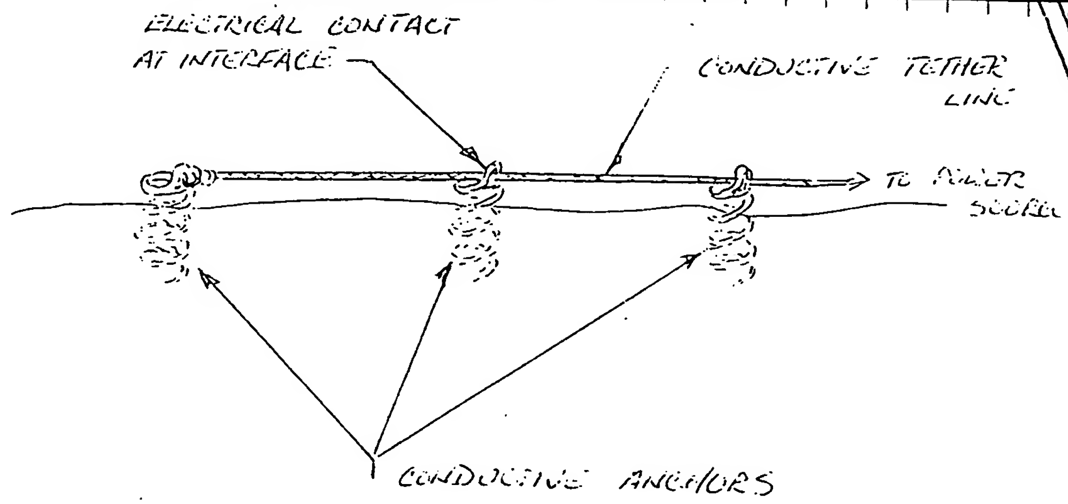


FIGURE 23

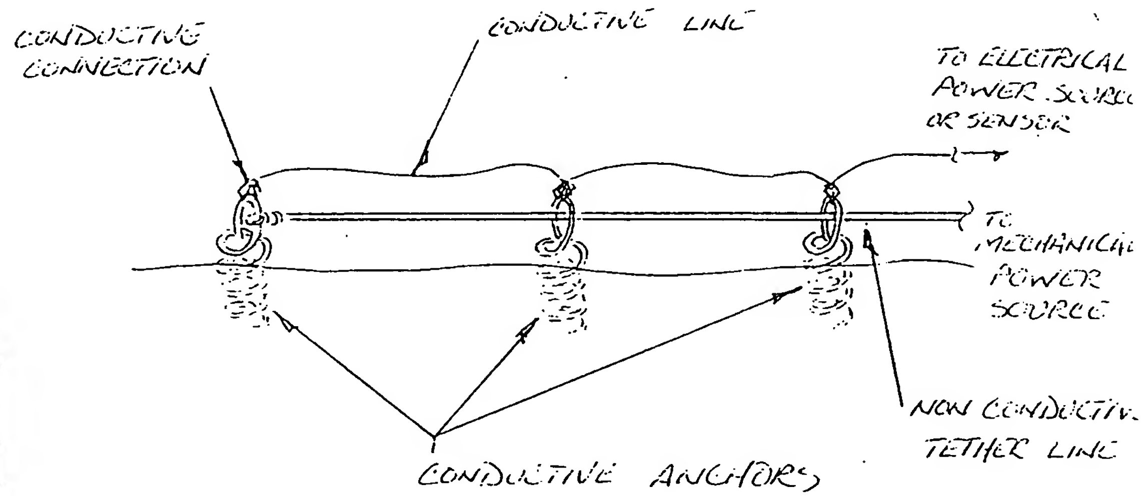


FIGURE 24

12/2/99

READ
&
UNDERSTOOD

12/19/99

TETHER LINE SUPPORT PAD / BRIDGE

CONFIDENTIAL

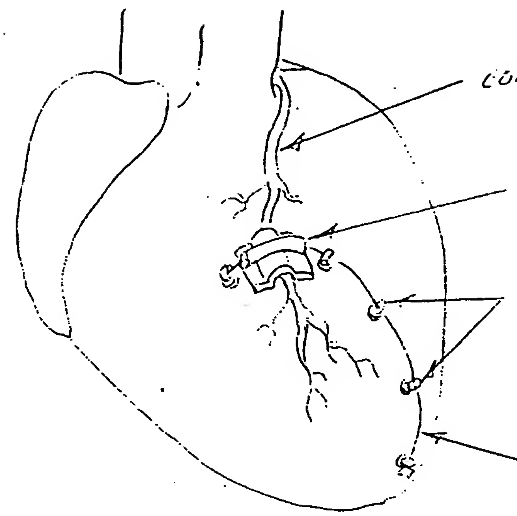


FIGURE 25

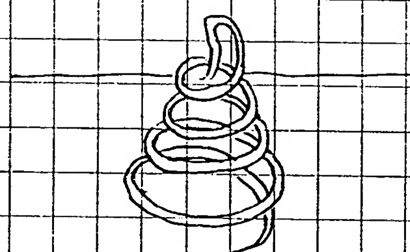
TETHER LINE CORONARY ARTERY BRIDGE.

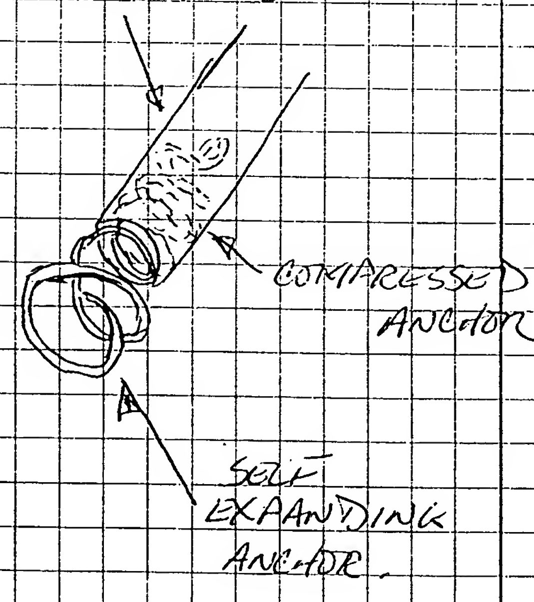
[signature] 12/2/99

READ/UNDERSTOOD [signature] 12/19/99

CONICAL COIL ANCHOR

TO IMPROVE THE LATERAL LOAD CAPABILITY OF THE ANCHOR, THE PART CAN HAVE A CONICAL, OR PYRAMID SHAPE TO CARRY GREATER LOAD DEEPER INTO THE MYOCARDIUM. THE COIL COULD BE MADE FROM NITINOL WIRE TO GIVE IT SHAPE MEMORY TO BE DELIVERED FROM A STRAIGHT, CYLINDRICAL TUBE, BUT WOULD EXPAND OUTWARD AS IT BURROWS INTO TISSUE.

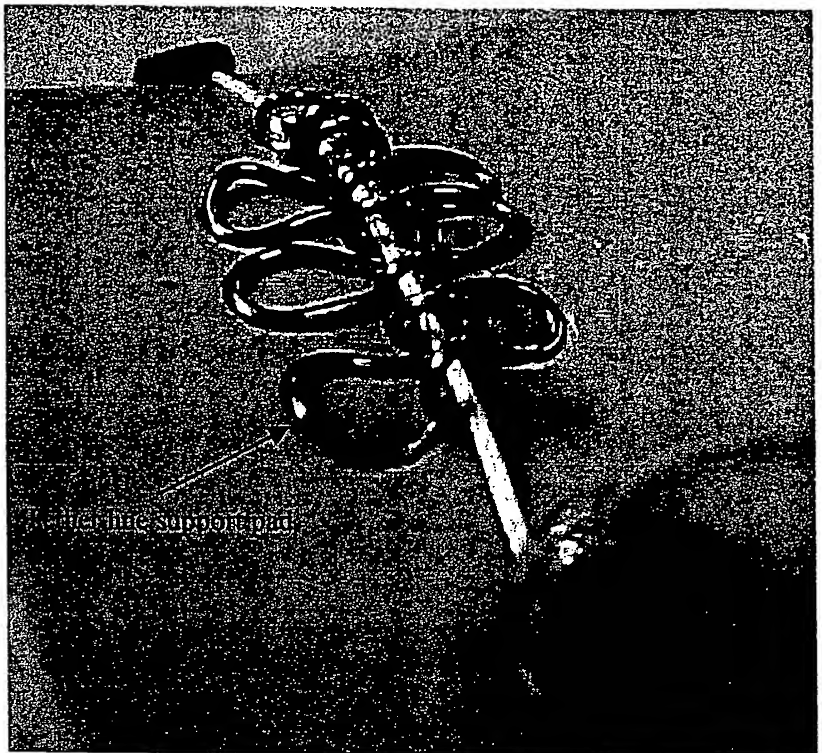




12/7/99

READ + UNDERSTOOD 12/17/99

TETHER LINE SUPPORT PAD/ STANDOFF



Note, support pad distributes the load from the tether line for reduced trauma to tissue.

Copper wire mock-up distributes tether line load. Nitinol support pads will allow folding to a smaller profile for thoracoscopic delivery.

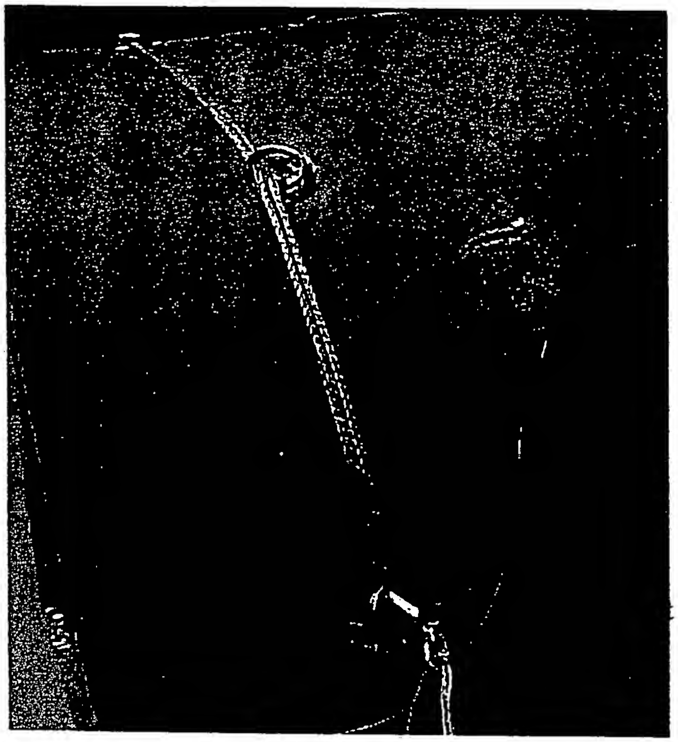
12/8/99

12-8-99

READ & UNDERSTOOD

12/19/99

DUAL LUMAN TERMINATION BUTTON (PS-1)



Dual lumen termination plug.

12/8/99

12-8-99

READ & UNDERSTOOD 12/19/99

TETHER LINE STAND-OFF

Tether line stand-off.

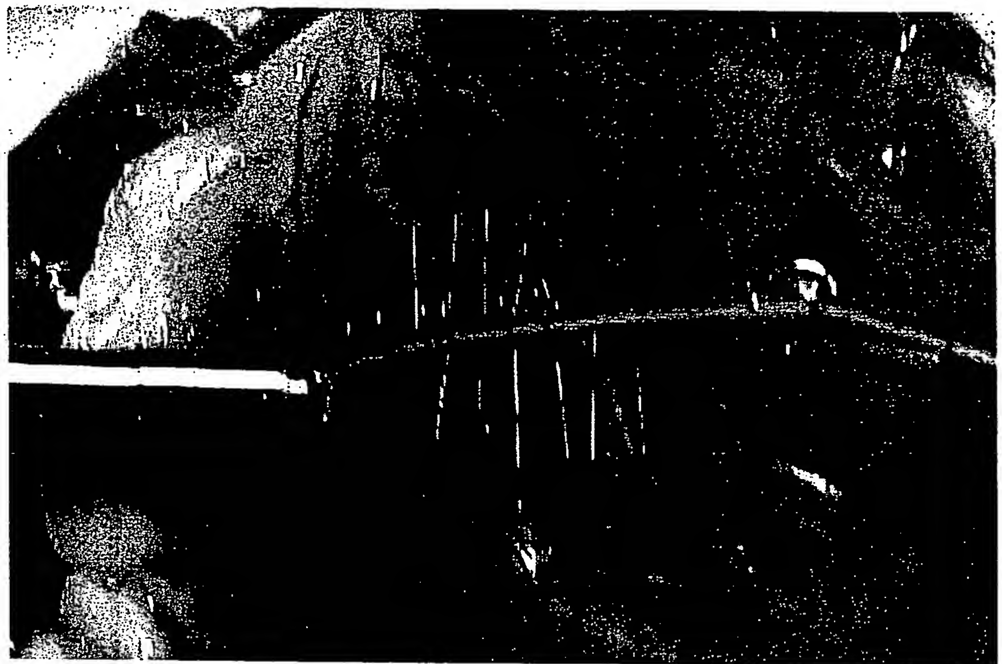


Figure 1: Nitinol tether line stand-off distributes epicardial load from the tether line.

Figure 2: Standoff can be delivered over the shaft of the anchor delivery system. The nitinol stand-off can be folded down around the delivery shaft and captured by a sleeve for smaller delivery profile.

DHO12/10/99 [signature] 12/13/99

READ & UNDERSTOOD [signature] 12/19/99

TETHER LINE STAND-OFF CONTINUED

Figure 3: Tether line stand-off is delivered over the tether line, capturing the line through the center coil.

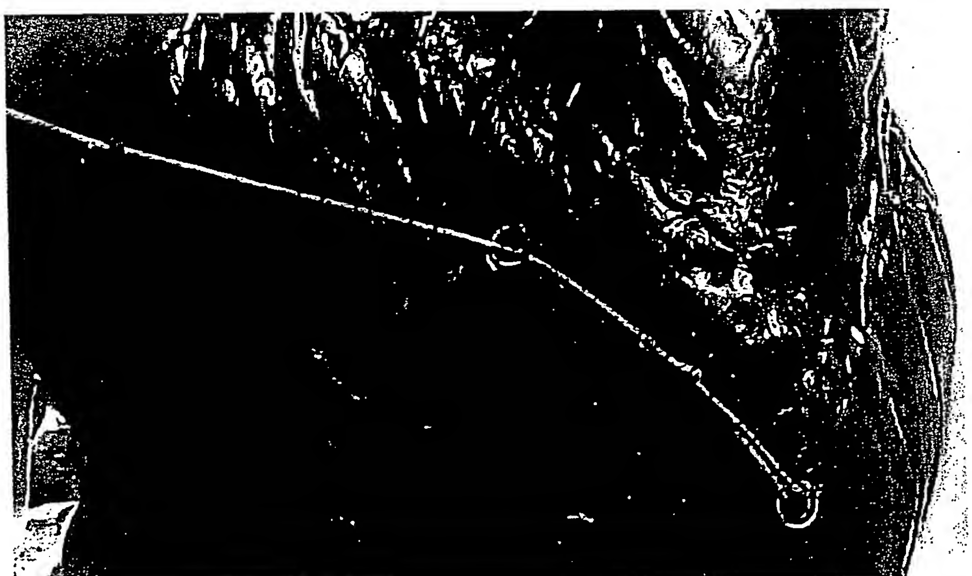


Figure 4: Stand-offs may be trimmed to varying lengths and spaced between anchors.

DHO12/10/99 12/13/99

READ & UNDERSTOOD 12/19/99

TETHER LINE STAND-OFF, CONTINUED

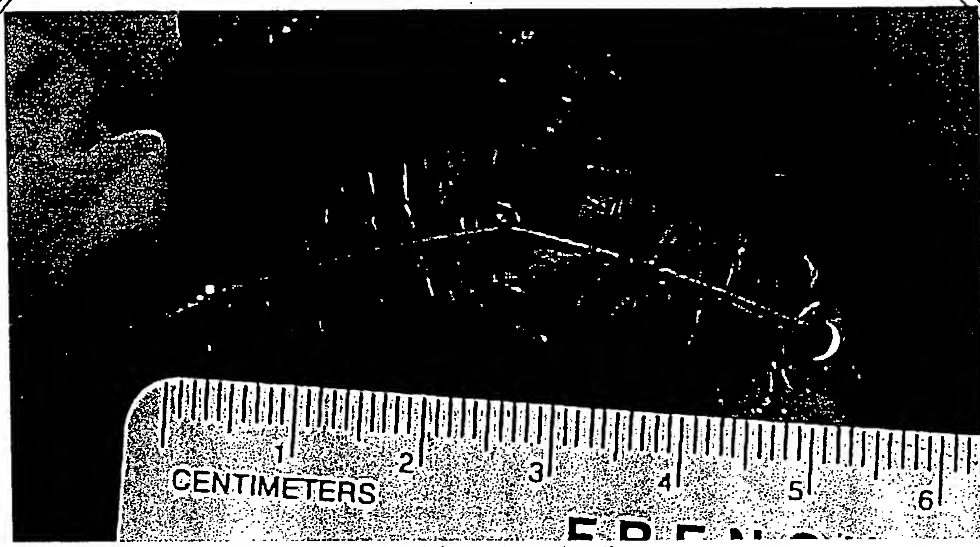


Figure 5: Stand-offs distribute the load from the tether line.

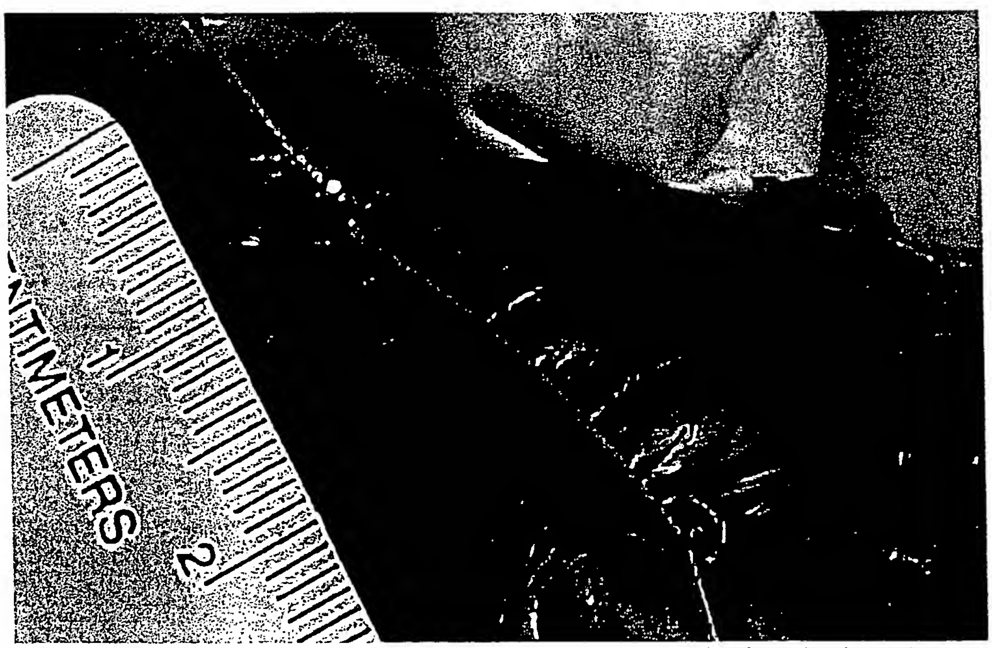


Figure 6: Stand-off allows tether line to freely slide, without cutting into the tissue. Legs of the stand-off follow the contour of the tissue and accommodate surface changes during the cardiac cycle.

DHO12/10/99

12/13/99

READ & UNDERSTOOD 12/19/99

CARDIAC HARNESS PATTERNS

Figure 1: Anchors and tether line can be arranged in a left hand helical pattern from the apex of the left ventricle to the ventricular septum.

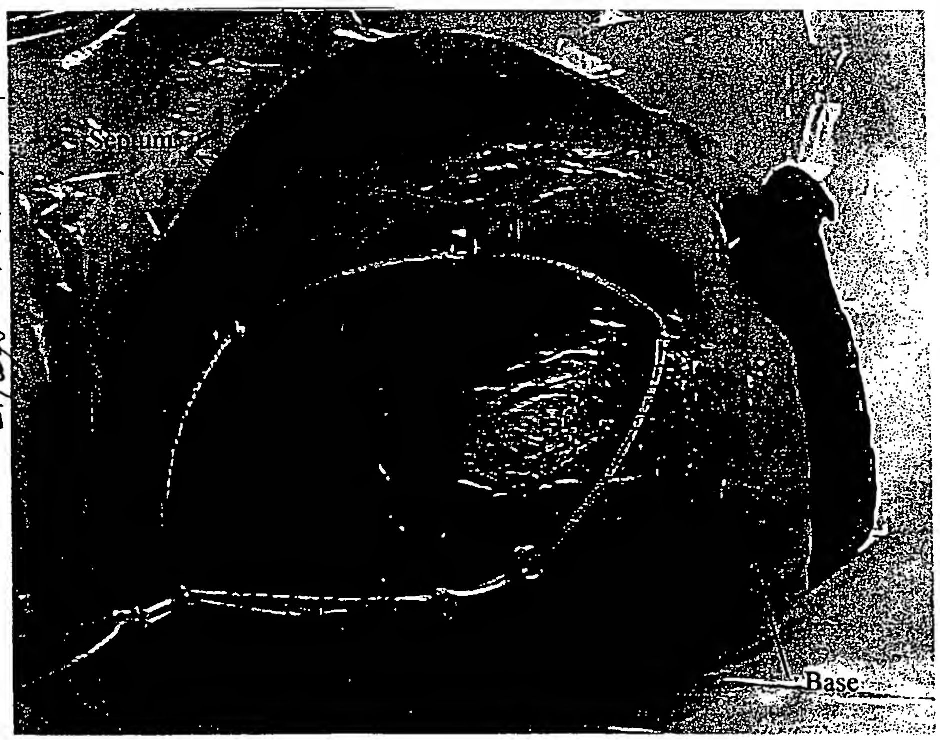


Figure 3: The harness can also be arranged in a continuous loop, to more evenly distribute the load to each anchor from the tensioned tether line. The harness may be a passive left ventricular assist device, or may be powered, to be an active assist device.

12/13/99 READ & UNDERSTOOD 12/19/99

CARDIAC HARNESS PATTERNS CONTINUED

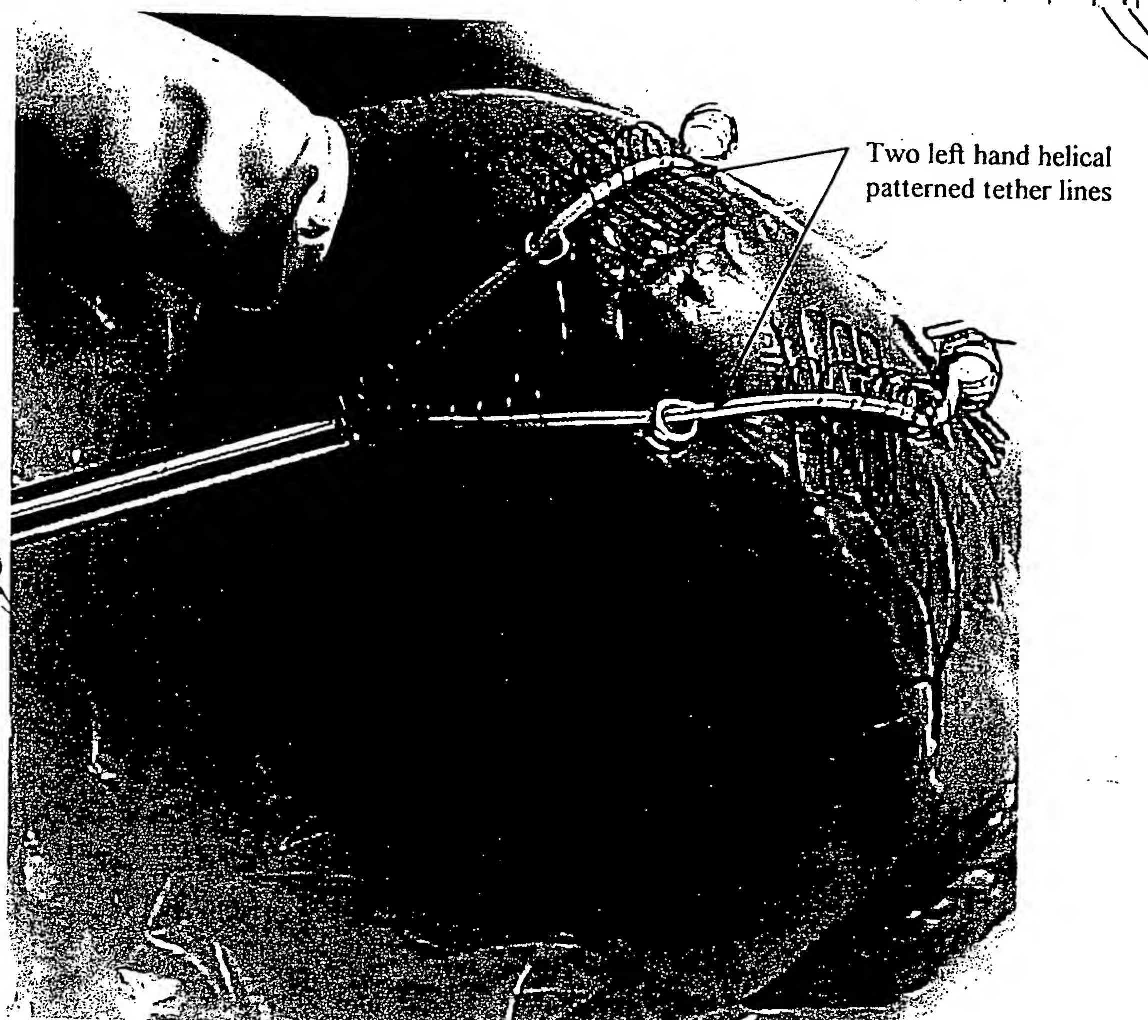


Figure 2: Multiple left hand helical patterns may be arranged on the left ventricle. As shown above, they may share a common end anchor and terminate as a passive harness, or be driven as an active ventricular assist.

DHG 12/13/99

12/13/99

READ + UNDERSTOOD 12/19/99

CARDIAC HARNESS PATTERNS

Figure 4: The pattern may start at the apex of the left ventricle and move toward the base of the heart

Figure 5: The pattern may then follow the base of the heart toward the septum.

DHO12/10/99

DHO 12/13/99

12/13/99

READ & UNDERSTOOD

12/19/99

CARDIAC HARNESS PATTERNS CONTINUED

Figure 6: The pattern may then run along the ventricular septum, back towards the apex.

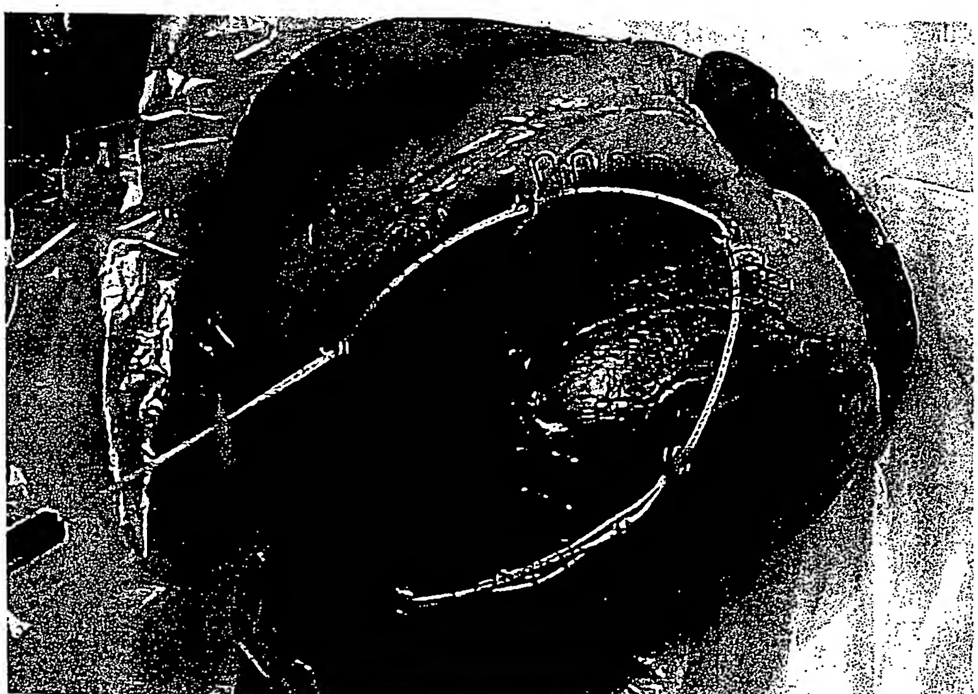


Figure 7: Anchors may have reinforcement if anchored into the septum.

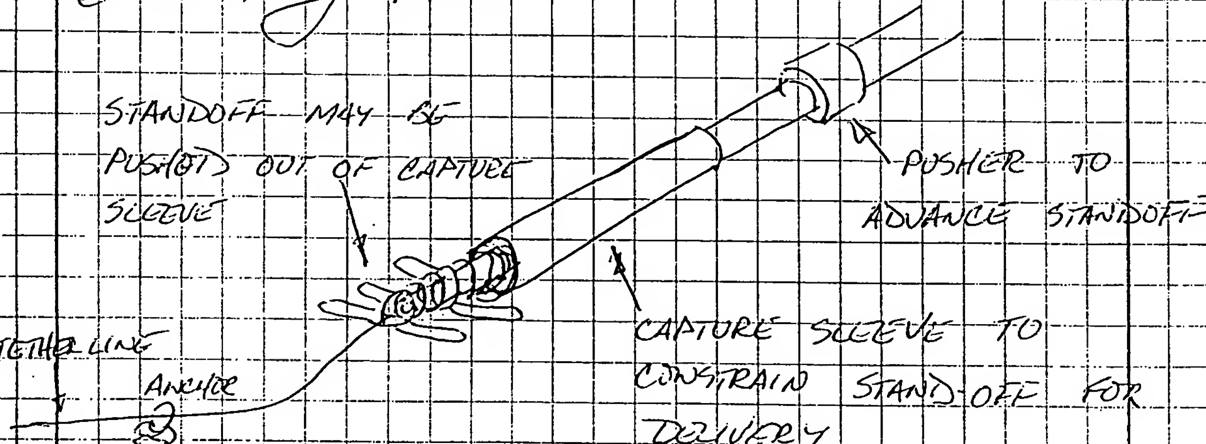
DHO12/10/99 12/12/99

READ + UNDERSTOOD 12/14/99

CARDIAC HARNESS PATTERNS CONTINUED

Figure 8: The tether line may be terminated at a common anchor, or connected to a power source.

12/13-99



12/13/99

READ & UNDERSTOOD 12/15/9

CARDIAC HARNESS WITH ACTIVE ASSIST (AUTOLOGOUS)

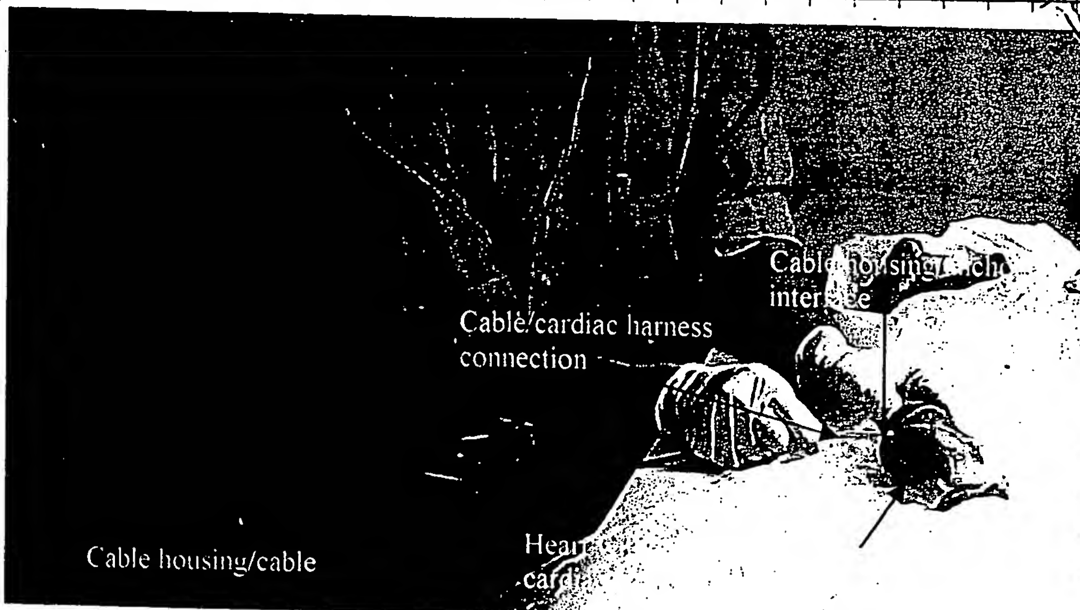


Figure 1: Active cardiac harness powered by bicep contraction.

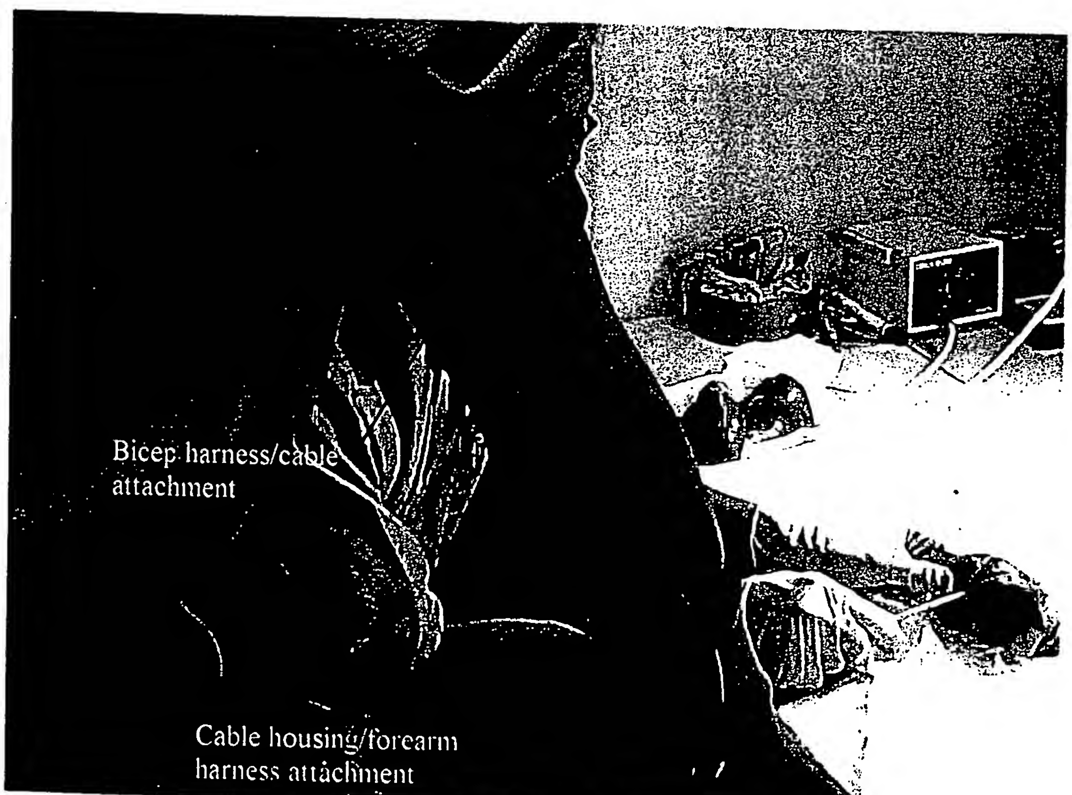


Figure 2: Cardiac harness is in relaxed (slack) state when forearm is extended.

12/15/99

READ + UNDERSTOOD 12/19/99

ACTIVE ASSIST HARNESS - CONTINUED

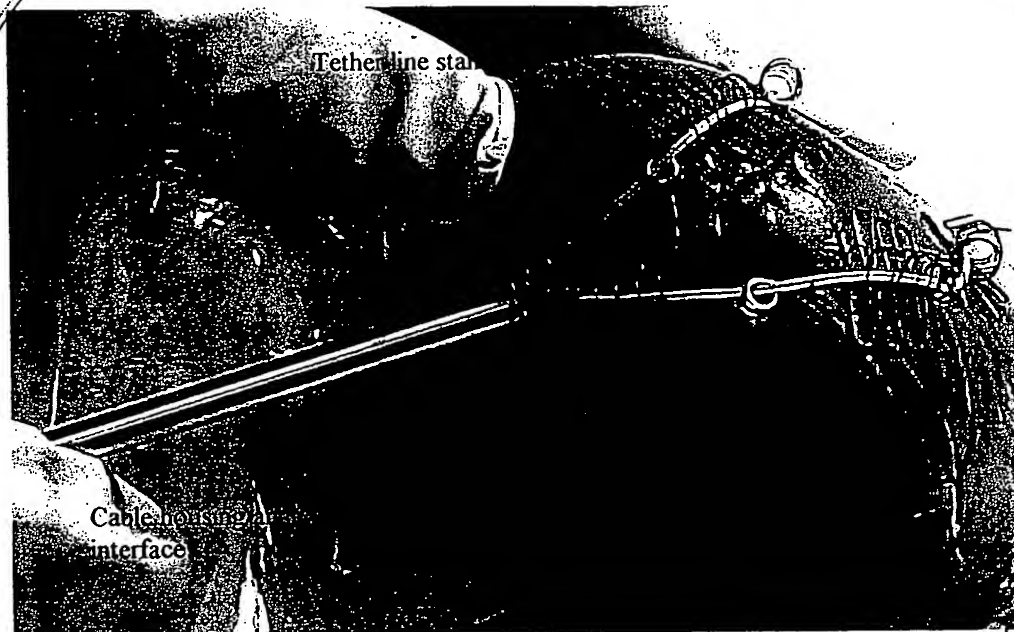


Figure 3: Cardiac harness is slack (end diastolic) state.

Figure 4: Bicep in flexed position, pulls on the cable to activate the cardiac harness.

12/13/99

READ & UNDERSTOOD 12/19/99

ACTIVE ASSIST HARNESS CONTINUED

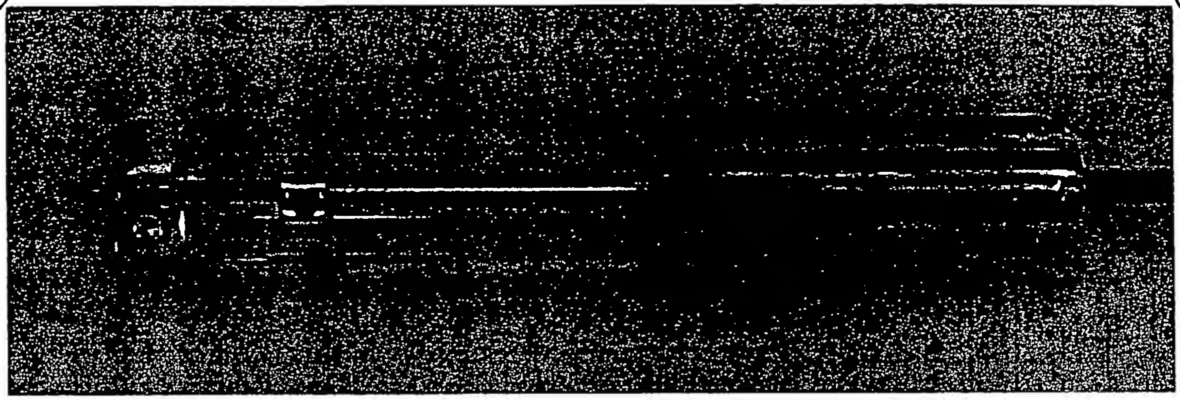
Figure 5: Cardiac harness tensioned by bicep flexure, compresses left ventricle by up to one centimeter.

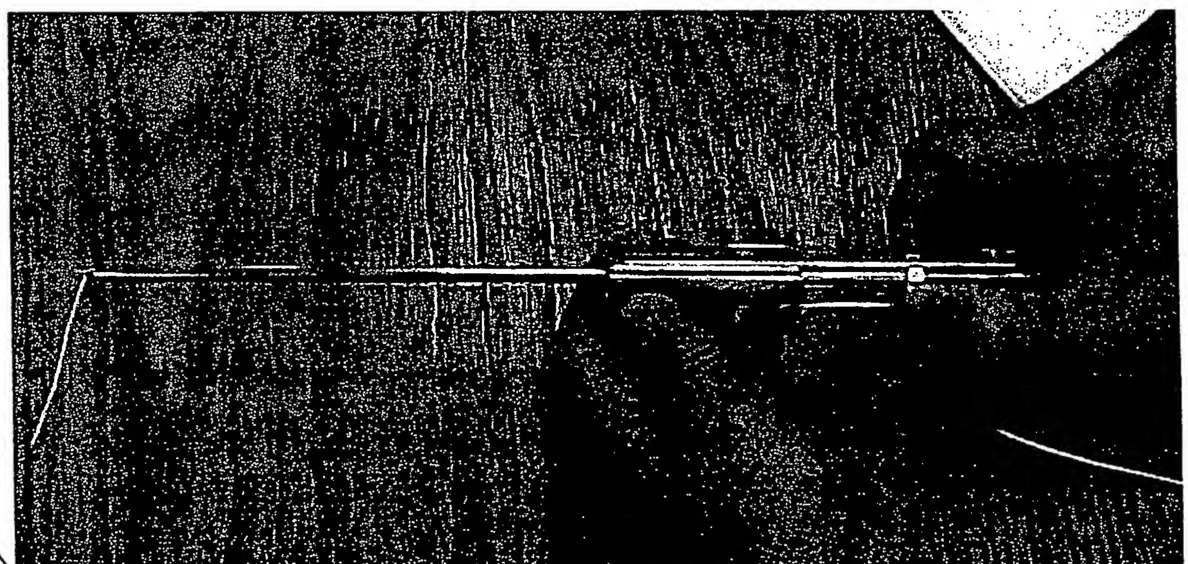
Figure 6: The diaphragm harness was also able to show approximately 0.5 to 1.0 centimeters of left ventricular contraction with expansion due to breathing.

12/13/99

READ & UNDERSTOOD 12/13/99

COIL ANCHOR DELIVERY DEVICE (SEE PAGE 5)





DHO 12/15/99

PROTOTYPE OF COIL ANCHOR DELIVERY SYSTEM COMPLETED BY DIETER 2 10-15-99 SUCCESSFULLY DELIVERS SINGLE ANCHORS OVER TETHER LINE.

12/15/99

READ + UNDERSTOOD 12/19/99

BARBED SHEET METAL ANCHORS

Sheet metal end anchors

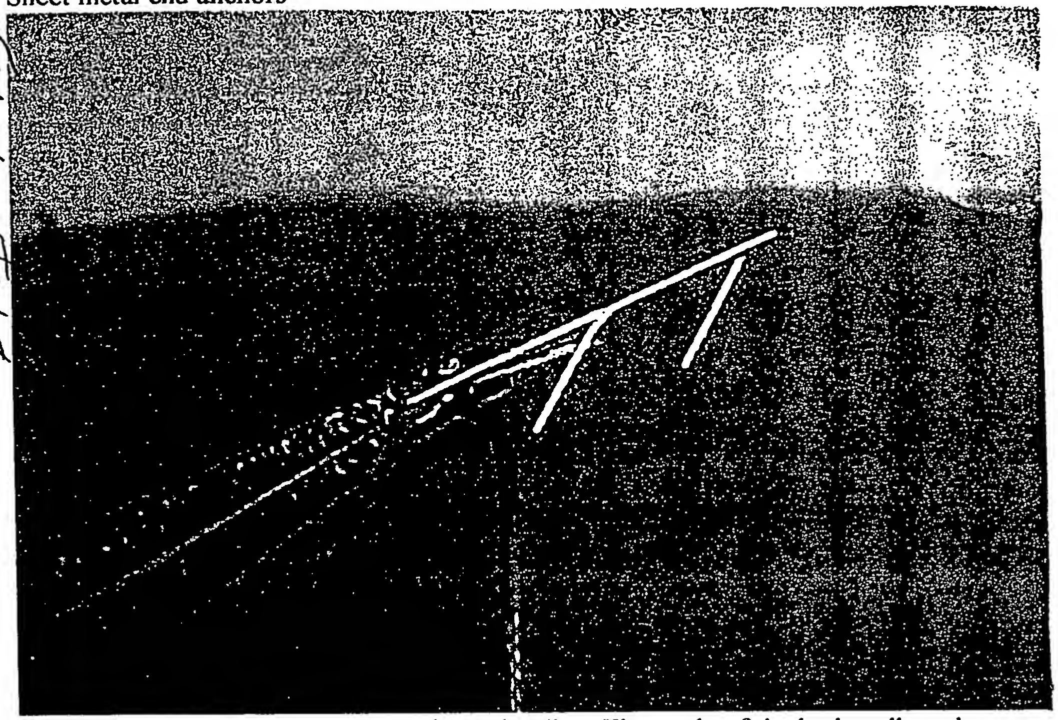


Figure 1: Sheet metal end anchor with tether line, The angle of the barbs, allow the anchor to dig deeper into the tissue with lateral loading. The forces are distributed throughout the anchor and tissue and more barbs may be added for higher loads.

Figure 2: Anchor in being loaded by the tether line through the middle guiding anchors. The sheet metal anchors may distribute and tolerate shear loading better than a coil type anchor, which may tip and may have a higher stress concentration.

12/17/99

READ & UNDERSTOOD

12/18/99

SHEET METAL ANCHORS

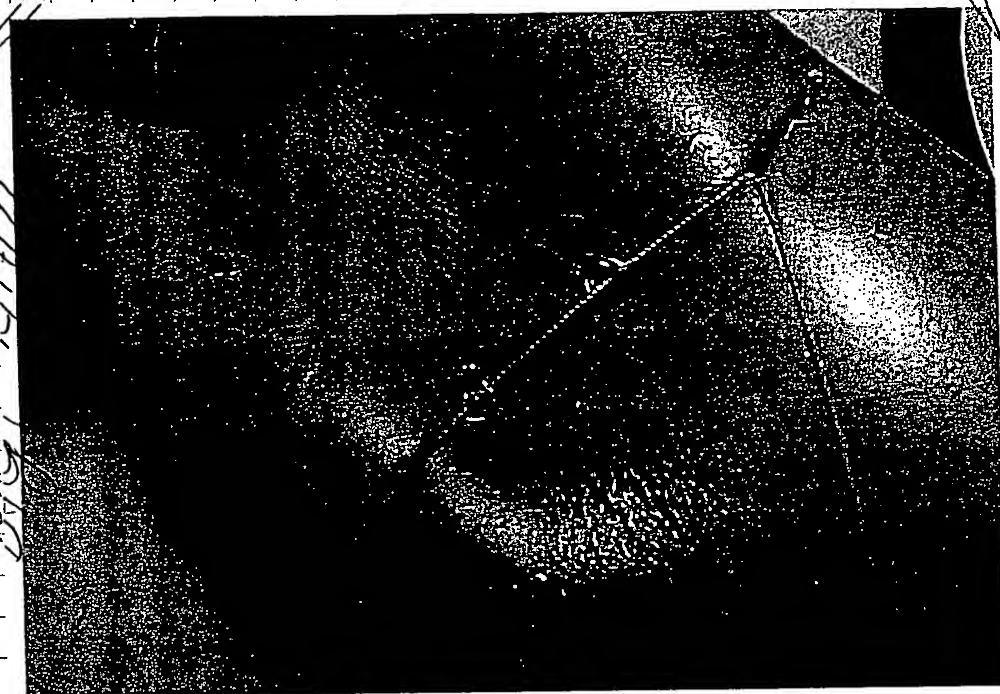


Figure 3: Sheet metal end anchors being tensioned with tether line.

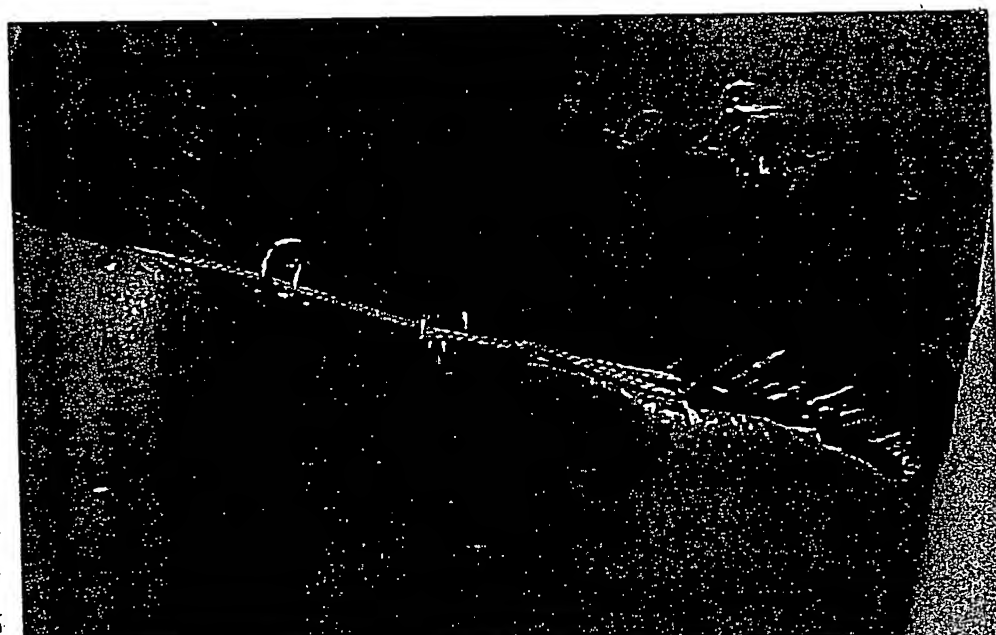


Figure 4: End anchors with extreme loading, buckling the foam model.

12/17/95

READ & UNDERSTOOD

12/19/95

SHEET METAL BARBED ANCHORS

Barbed anchors

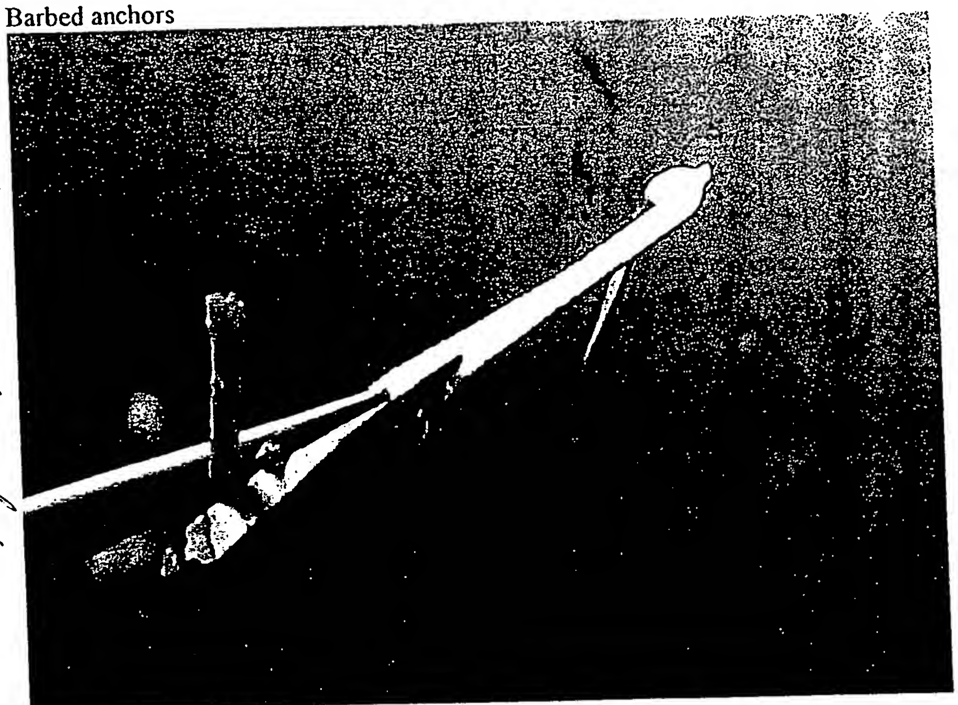


Figure 1: Sheet metal end anchor.

Figure 2: Angle of barbs distribute forces with shear loading.

DHO122099

DHG 12/21/99

READ & UNDERSTOOD

Daniel H. G. 12/21/99

1/17/00

BARBED ANCHORS

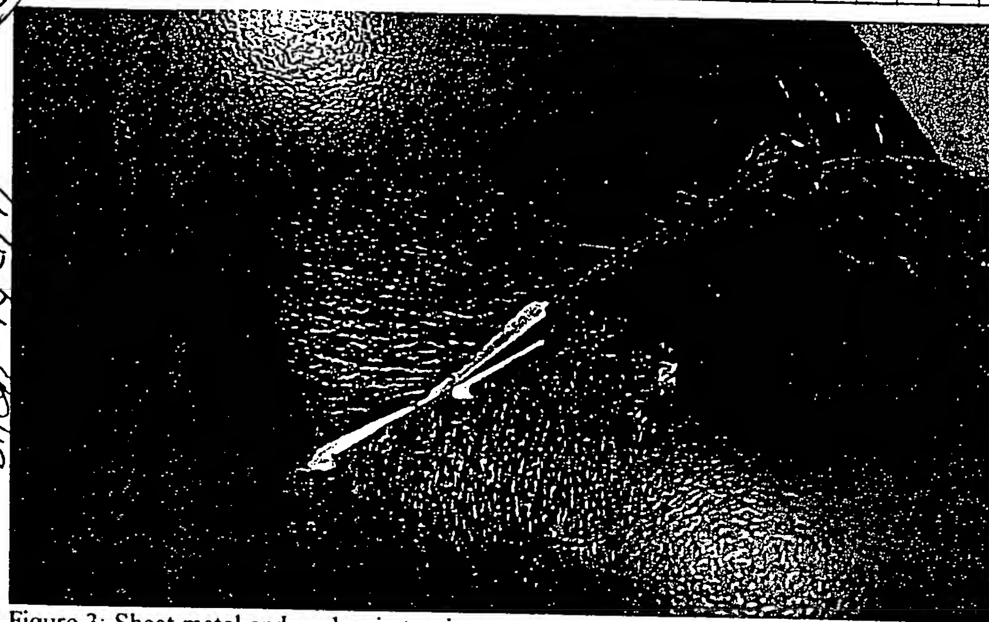


Figure 3: Sheet metal end anchor in tension.

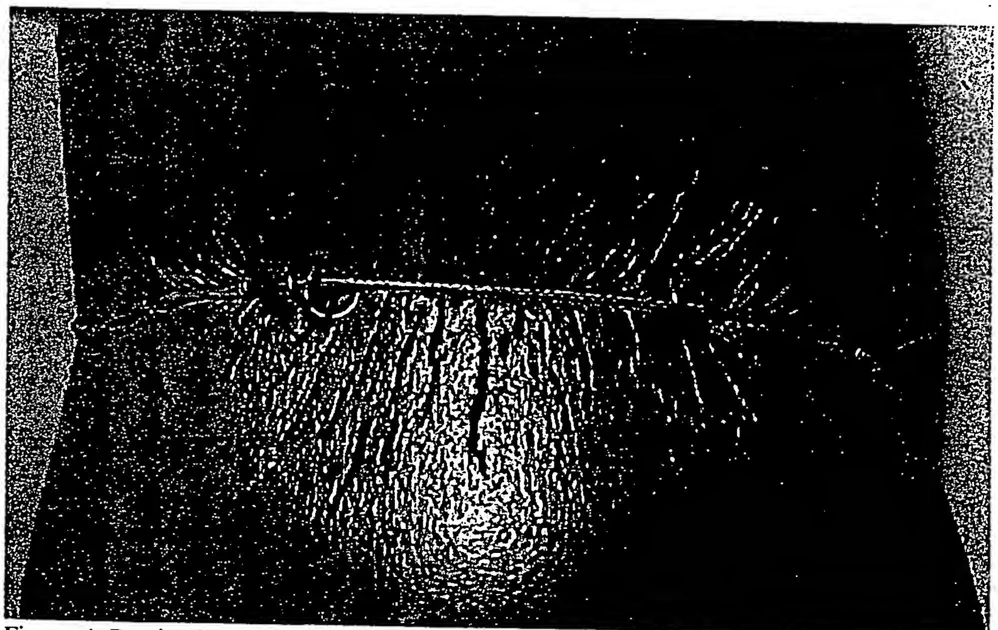


Figure 4: Passive harness with sheet metal barbed anchors and guiding coil anchors.

DHO122099

12/21/99

READ + UNDERSTOOD

1/17/00

CONICAL ANCHORS

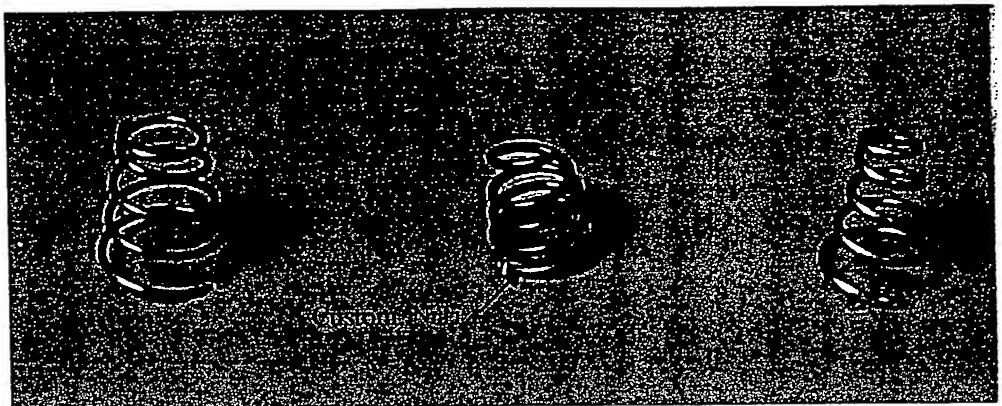


Figure 1: Conical anchors (2 spring steel and 1 Nitinol).

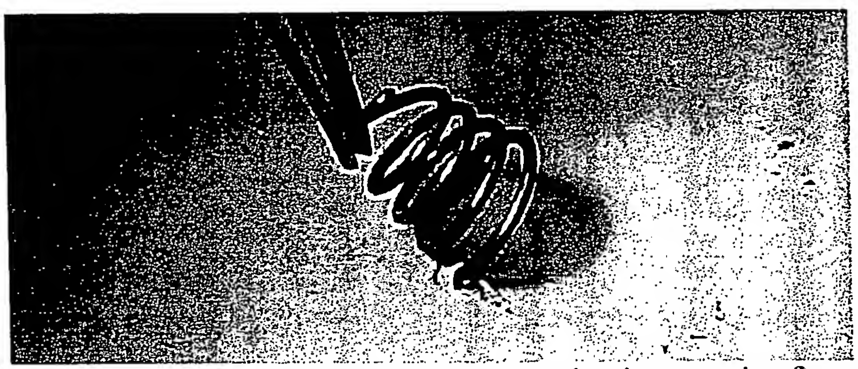


Figure 2: 20 threads per inch Nitinol reverse tapered anchor, wound on fixture.

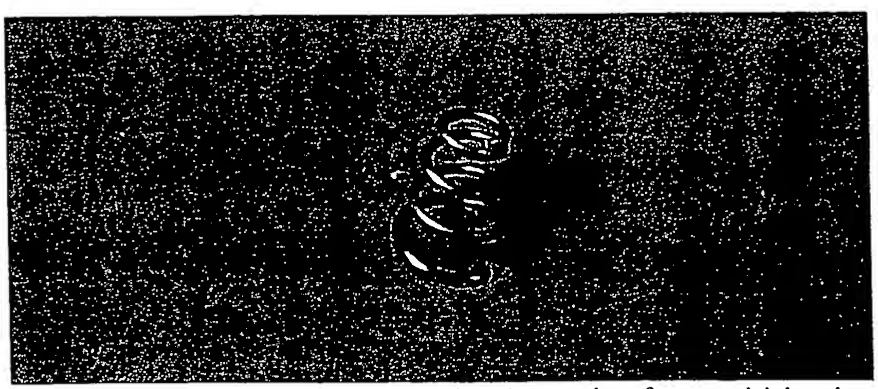


Figure 3: Spring steel tapered anchor easily advances into foam model, but does not collapse down into capture tube.

DHO122199

12/21/99 READ UNDERSTOOD 1/17/00

CONICAL ANCHORS

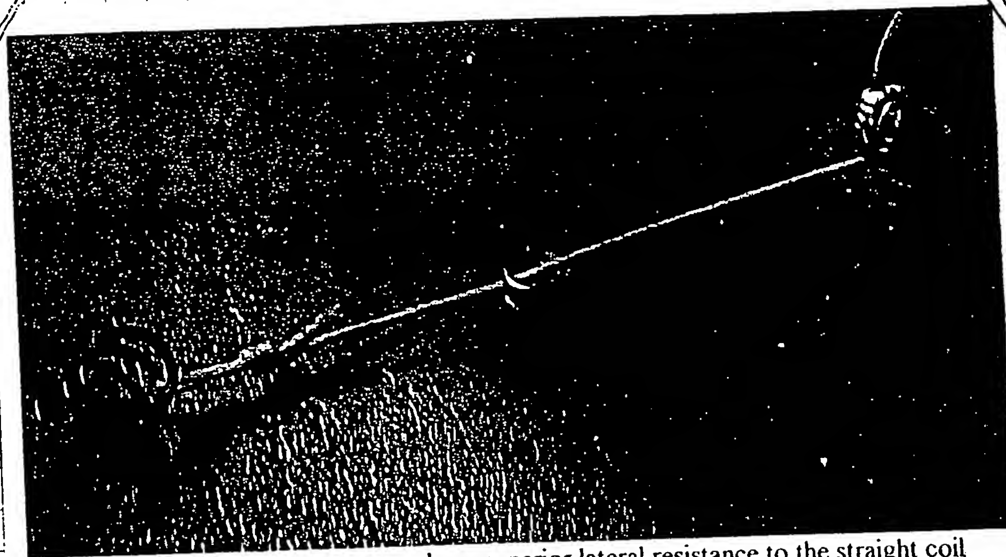


Figure 4: Conical anchors appear to have superior lateral resistance to the straight coil anchors.

DHG 12/21/99

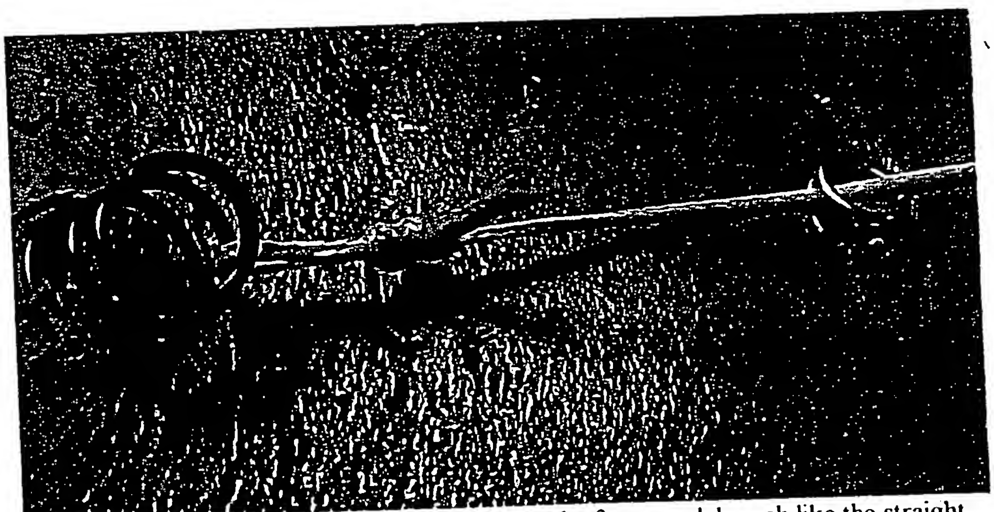


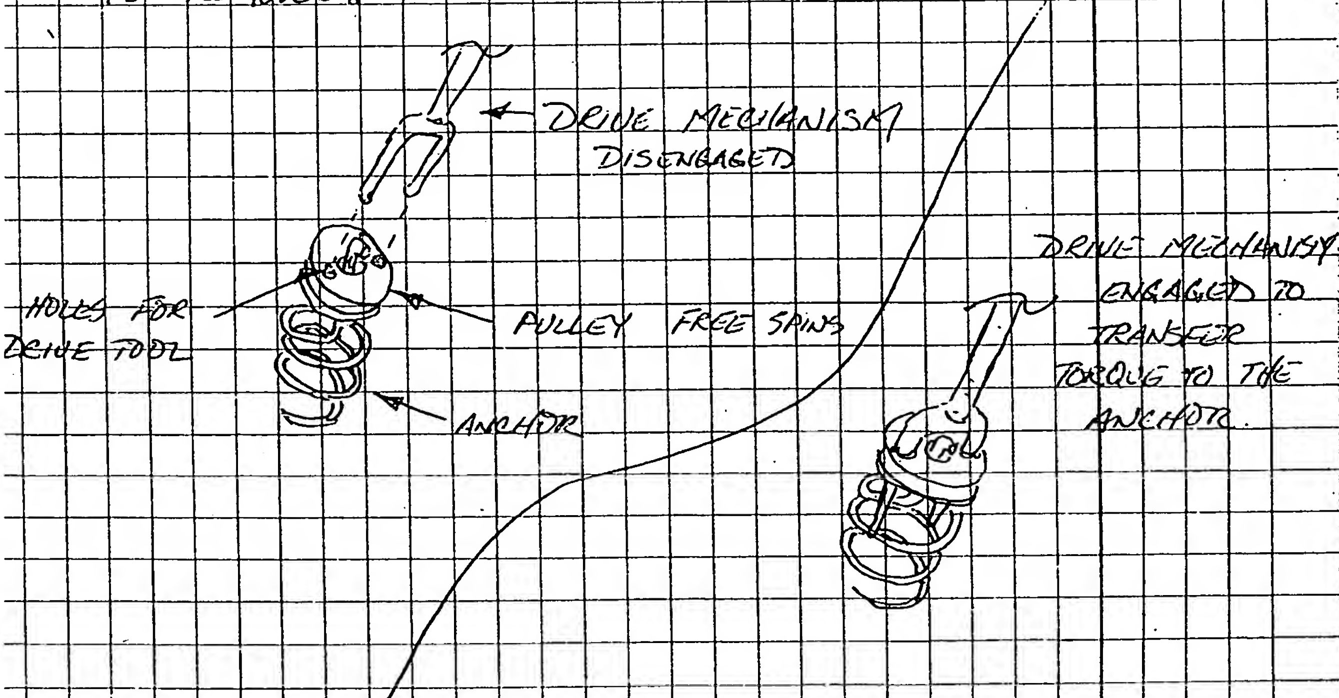
Figure 5: The spring steel anchors advance into the foam model much like the straight coil counter parts, but the nitinol anchors appear to flexible to drive into the foam mode cleanly. The nitinol conical anchor does not easily self thread into the foam, the coils deflect with the resistance of the foam.

DHO122199

David H. G. 12/21/99 READ & UNDERSTOOD Diane Carter 1/17/00

ANCHORS WITH PULLEYS

TO ASSIST IN REDUCING FRICTIONAL FORCES WITHIN THE HARNESS SYSTEM, SOME OF THE MIDDLE ANCHORS MAY WANT TO HAVE PULLEYS MOUNTED ON THE TOP SIDE OF THE ANCHOR TO ALLOW THE TETHER LINE TO MOVE FREELY RELATIVE TO THE ANCHOR. THE PULLEY MAY HAVE HOLES OR SLOTS THROUGH THE DISK PORTION TO ALLOW TORQUE TRANSFER TO THE ANCHOR FOR DELIVERY, BUT ALLOW THE PULLEY TO FREEWHEEL AFTER THE DRIVE TOOL IS REMOVED.

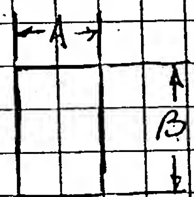


Daniel A. [illegible] 12-22-99

READ + UNDERSTOOD [signature] 1/17/00

ELECTROPOLISH LASERCUT COILS (12-16-99)

LASERCUT STAINLESS STEEL COIL ANCHORS WERE TAKEN TO ALLBRITE TO ROUND OFF THE SHARP CORNERS OF THE CUT PARTS VIA MORE AGGRESSIVE ELECTROPOLISHING. DAVE MORTENSON HAD RANDEL WORK WITH ME TO DEVELOP THE POLISHING PROCESS.



CROSS SECTION

	VOLTAGE	CURRENT	TIME
#1)	7.5-8 V	10A	3 MIN
#2)	7.5-8 V	10A	3+3 MIN
#3)	10 V	20A	2 MIN
#4)	10 V	20A	3 MIN

PARTS	A DIM	B DIM	AREA
I RAW COIL	.015"	.023"	.00035 IN^2
II FIRST PASS #1 23min	.014	.022	.00031 IN^2
III #2	.007-.010	.015-.016	.00011 - .00016 IN^2
IV #4	.010-.011	.017-.018	.00017 - .0002 IN^2

ROUND WIRE = .023" ø AREA $\frac{\pi D^2}{4} = \frac{3.1416(.023)^2}{4} = .00042$

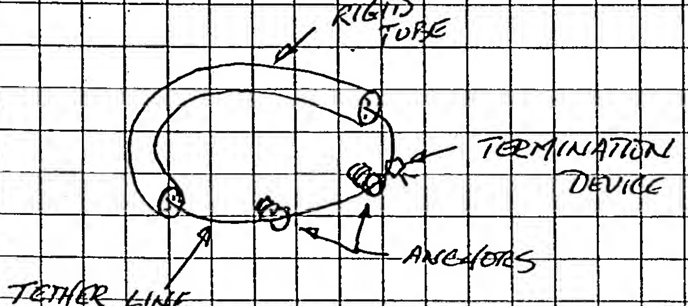
Daniel [signature] 12-22-99

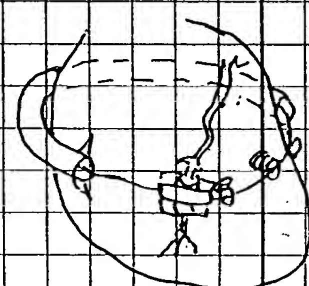
READ + UNDERSTOOD [signature] 1/17/00 DMC

Diane Carter 1/17/00 [signature]

RIGID TUBE RIGHT SIDE SUPPORT

THERE MAY BE ADVANTAGES TO REDUCING WALL STRESS BY USING A COMPLETE LOOP HARNESS AROUND THE ENTIRE HEART (SEE PAGE 16). THE DISADVANTAGE IS THAT THE COMPLETE LOOP HARNESS MAY CONSTRICT AND RESTRICT THE RIGHT VENTRICLE IN ADDITION TO THE LEFT VENTRICLE. A METHOD TO ISOLATE THE TETHER LINE FROM THE RIGHT VENTRICLE IS TO HAVE A CURVED ~~SO~~ DHA 12-24-99 RIGID TUBE RUNNING AROUND THE BACK, OR RIGHT SIDE OF THE HEART (L. LAU 12/21/99). THE RIGID TUBE WOULD ALLOW EASY MOVEMENT OF THE TETHERLINE AND ELIMINATE OR REDUCE THE RESULTANT FORCE LOADING ON THE ANCHORS OF THE LEFT VENTRICLE.



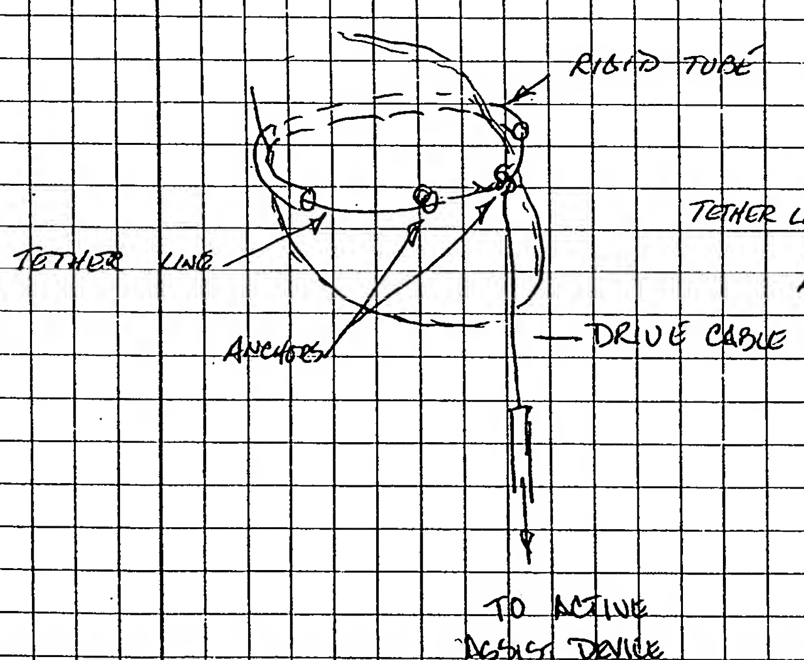


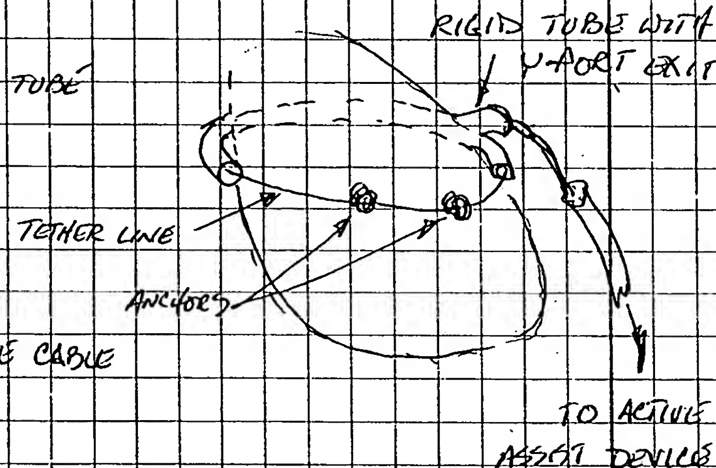
[signature] 12/24/99

READ & UNDERSTOOD [signature] 1/17/00

RIGID TUBE WITH ACTIVE HARNESS

THE RIGID TUBE AROUND THE BACK SIDE OF THE HEART MAY BE USED WITH AN ACTIVE HARNESS AS WELL AS WITH THE PASSIVE HARNESS. THE ACTIVE HARNESS MAY BE DRIVEN FROM ONE OF THE ANCHOR POINTS, OR MAY BE DRIVEN FROM A "Y" JOINT OF THE RIGID TUBE. WHEN DRIVEN FROM WITHIN THE CAPTURE TUBE, THE 'PULL' OUT FORCE OF THE ANCHORS IS MINIMIZED.





[signature] 1-3-00

READ & UNDERSTOOD

[signature]
1/17/00

ANCHOR PULL FORCE CHARACTERIZATION

	DIMENSIONS DIA, LENGTH WIRE DIA IN INCHES	STRAIGHT PULL FORCE lbF		LATERAL PULL FORCE lbF	
1)	.092 X .288 .015 Ø	1.2	CORED	1.6	CORED
2)	.092 X .300 .015 Ø	1.4	CORED	1.4	CORED
3)	.092 X .296 .015 Ø	1.3	CORED	1.4	CORED
4)	.092 X .325 .015 Ø	1.4	CORED	1.6	CORED
5)	.123 X .295 .013 - .014 Ø	1.7	DEFORMED	1.8	DEFORMED FURTHER
6)	.123 X .310 .013 - .014 Ø	1.8	DEFORMED	1.7	ABOUT THE SAME
7)	.123 X .290 .0135 - .014 Ø	1.5	CORED	1.6	CORED
8)	.123 X .230 .013 - .014 Ø	1.5	CORED	1.7	DEFORMED
9)	.155 X .320 .023 Ø	2.0	CORED	2.2	CORED
10)	.155 X .290 .023 Ø	1.8	DID NOT CORE	2.5	CORED
11)	.154 X .330 .023 Ø	2.4	CORED	2.6	CORED
12)	.154 X .325 .023 Ø	2.8	CORED	2.2	CORED

[signature] 1/12/00

READ & UNDERSTOOD [signature] 1/17/00

ANCHOR PULL FORCE CHARACTERIZATION

	DIMENSION DIA, LENGTH WIRE DIA IN INCHES	STRAIGHT PULL FORCE lbF	LATERAL PULL FORCE lbF
13)	.155 X ~~.320~~ .310 DHG 1-12-00 .023 ϕ	2.3 CORED	2.6 CORED
14)	.155 X .312 .023 ϕ	2.4 CORED	2.3 CORED
15)	.155 X .325 .023 ϕ	2.4 CORED	2.4 CORED
16)	.154 X .320 .023	2.4 CORED	2.4 CORED

[signature] 1-12-00

ANCHORS 1-4 STRAIGHT COIL

ANCHOR 5-8 STRAIGHT COIL

ANCHORS 9-12 SOLDERED SINGLE SHOT STRAIGHT COIL

ANCHORS 13-16 MODIFIED CS-1 REVOLVER ANCHOR

[signature] 1/12/00

READ + UNDERSTOOD [signature] 1/17/00

SIX SHOOTER ANCHOR DELIVERY SYSTEM

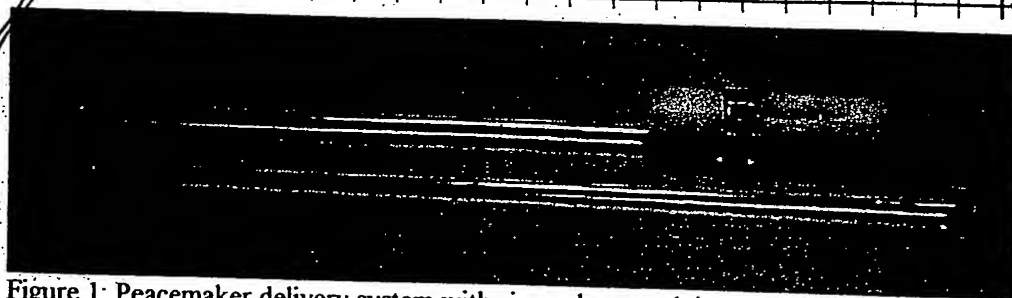


Figure 1: Peacemaker delivery system with six anchor revolving storage magazine and slotted drive mechanism.

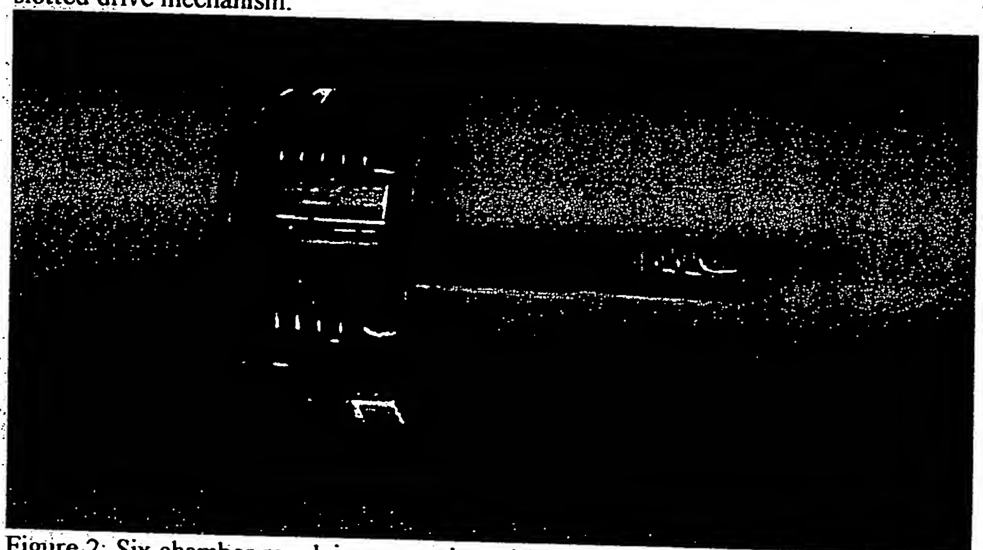


Figure 2: Six chamber revolving magazine with anchor in introduction slot.

1/14/00

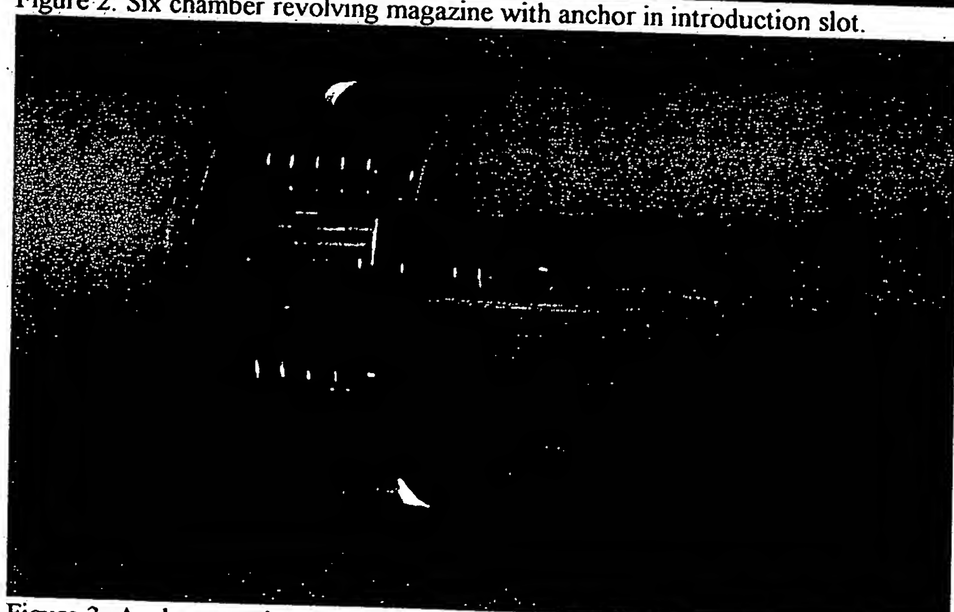


Figure 3: Anchor entering a chamber in the revolving magazine.

1-14-00

READ & UNDERSTOOD

1/17/00

PEACEMAKER DELIVERY SYSTEM - CONT

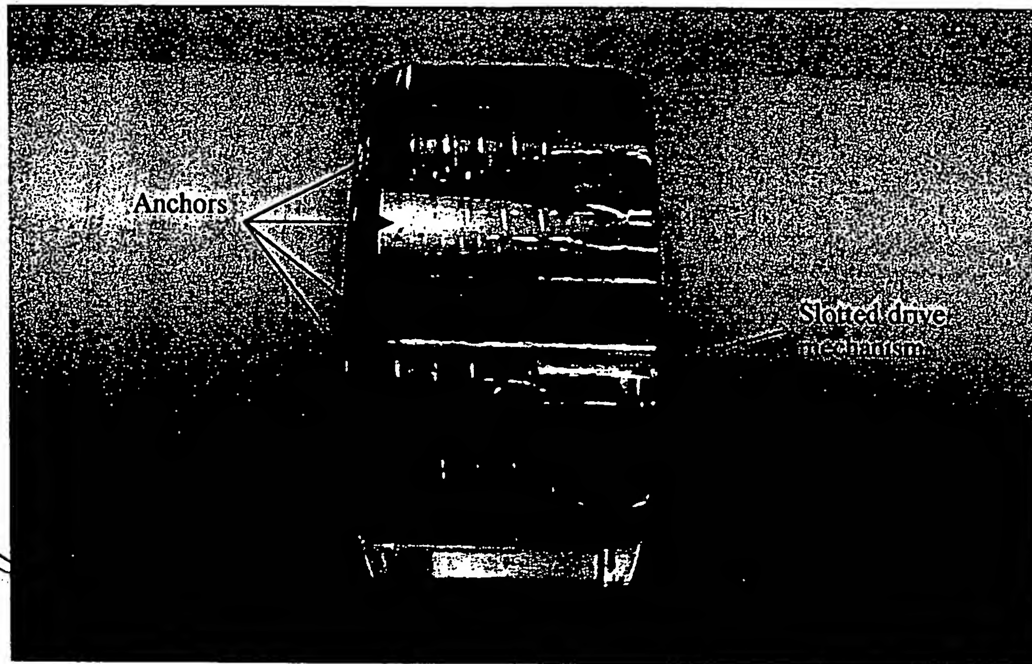


Figure 4: Drive mechanism engaging with the loop end of an anchor in the chamber.

Figure 5: First anchor is driven into the foam model with tetherline fed through a side port in the threaded tip.

1/14/00

1-14-00

READ & UNDERSTOOD

1/17/00

MULTI ANCHOR DELIVERY SYSTEM - CONT

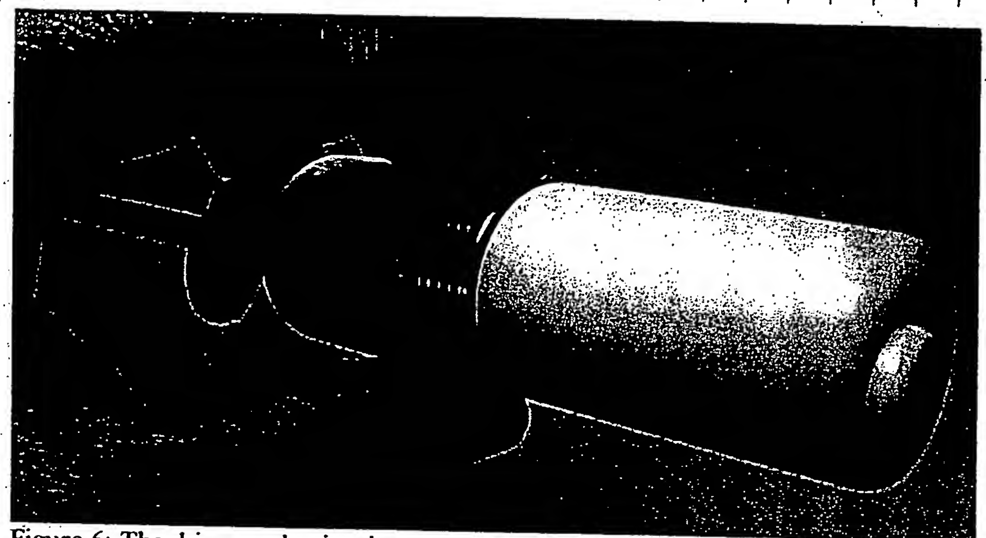


Figure 6: The drive mechanism is retracted and the revolving magazine is rotated to align the next anchor with the anchor delivery bore.

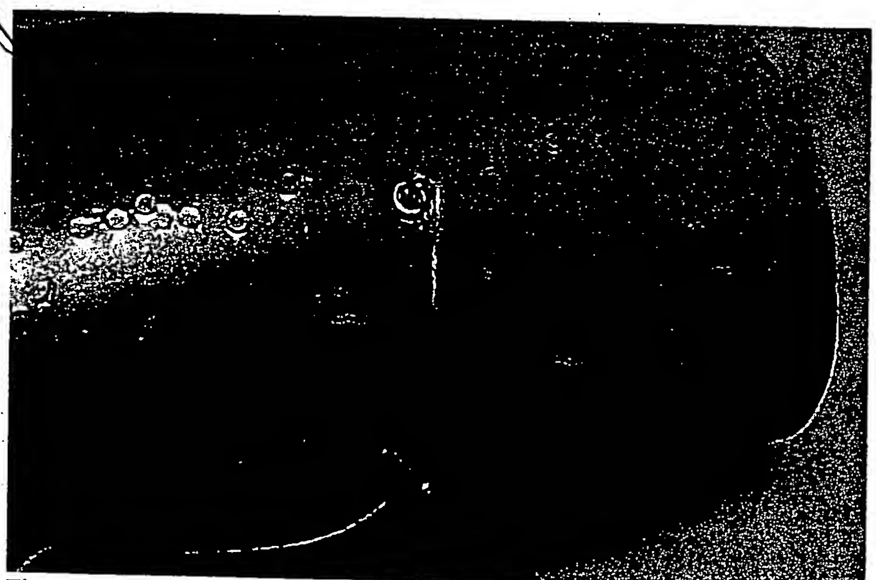


Figure 7: The drive mechanism is reinserted into the delivery system, a next location is identified and the second anchor is delivered into the foam model.

1/14/00

Darrell H. G. 1/14/00

READ + UNDERSTOOD Diane Carter 1/17/00

MULTI ANCHOR DELIVERY SYSTEM

Figure 8: The third anchor is indexed into position and delivered at the next location.

Figure 9: The fourth anchor is indexed into position and the location is identified.

1-14-00 READ + UNDERSTOOD 1/17/00

PEACEMAKER - CONT

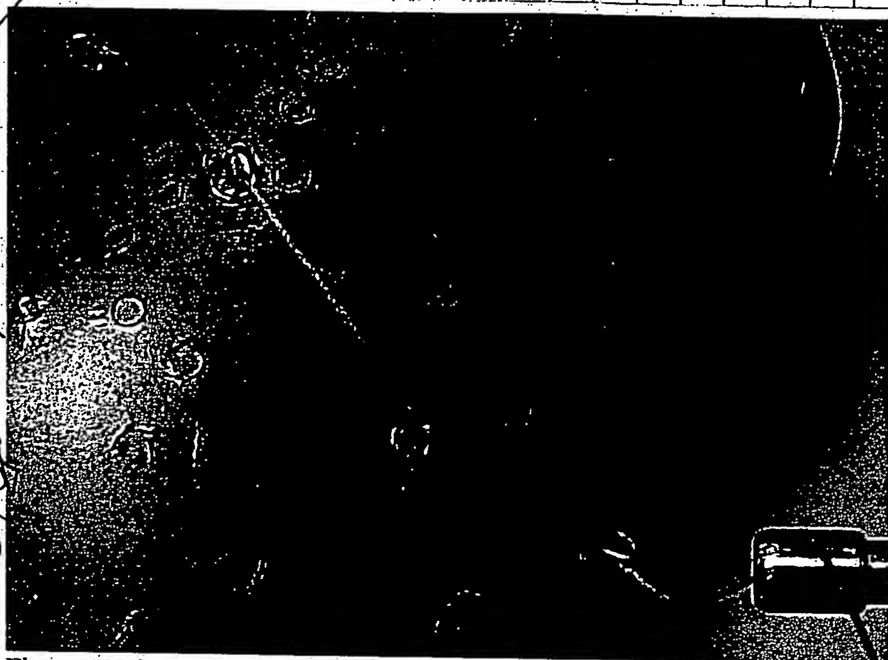


Figure 10: Once the fourth (and final in this case) anchor is inserted, the tetherline is check to confirm free movement through the anchor loops.

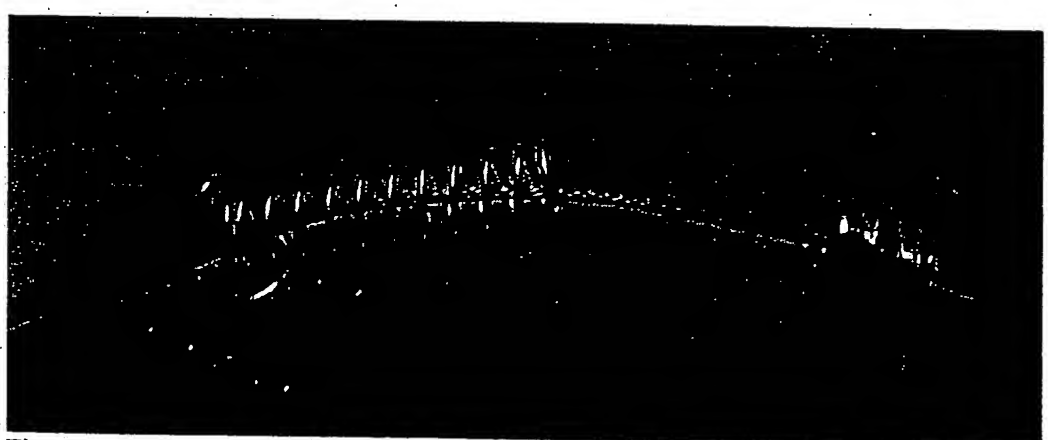


Figure 11: A compression spring and termination device are added ~~to the tetherline~~ for end termination.

1-14-00

READ
+ UNDERSTOOD

1/17/00

MULTI ANCHOR DELIVERY - CONT

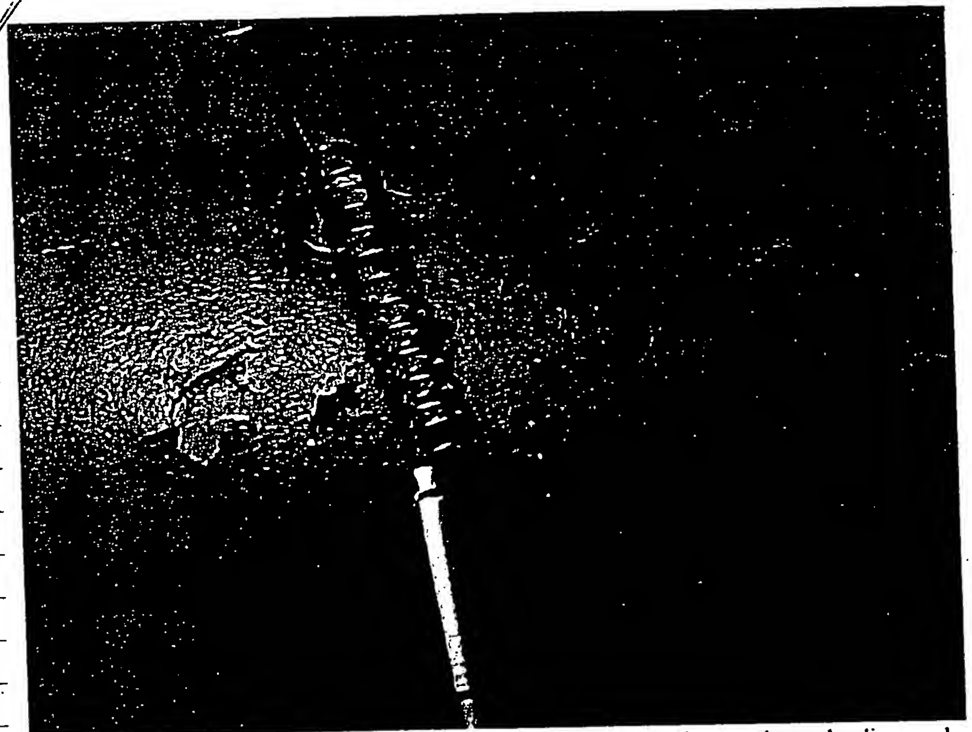


Figure 12: The end termination tightening tool is advanced over the tetherline and engaged with the termination device.

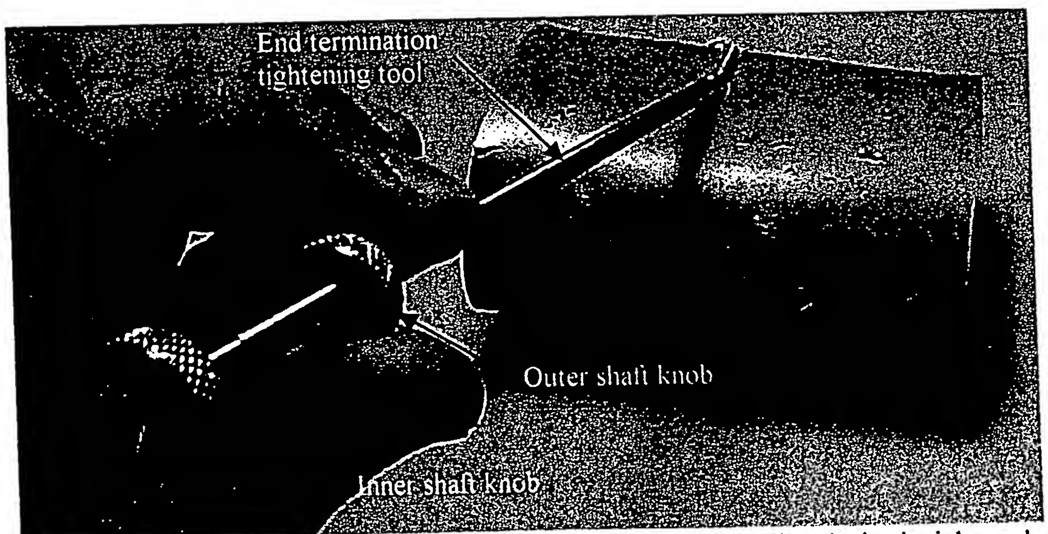


Figure 13: The tension of the tetherline is adjusted and the termination device is tightened by holding the outer shaft knob steady, while turning the inner shaft knob clockwlse,

1/14/00

READ & UNDERSTOOD

1/17/00

MULTI ANCHOR DELIVERY - CONT

Figure 14: Harness with compression spring in series will decrease the shock of the tetherline tensioning at end diastole and stored energy in the spring should assist the initial contraction of systole.

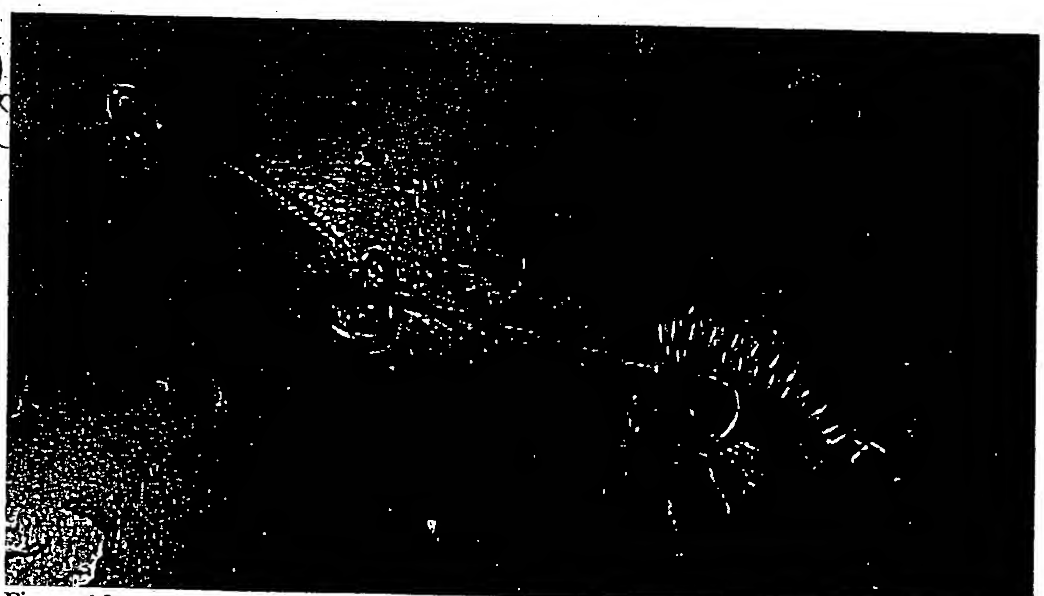


Figure 15: .125" diameter compression spring stores approximately 1 pound of force with 1 centimeter of compression. Note, the end of the .125" diameter compression spring does not seat square with the anchor loop and may corkscrew into the loop.

1-14-00

READ
✓ UNDERSTOOD

1/17/00

MULTI ANCHOR DELIVERY SYSTEM - CONT

Figure 16: The termination device may also be loosened to readjust the tension in the harness.

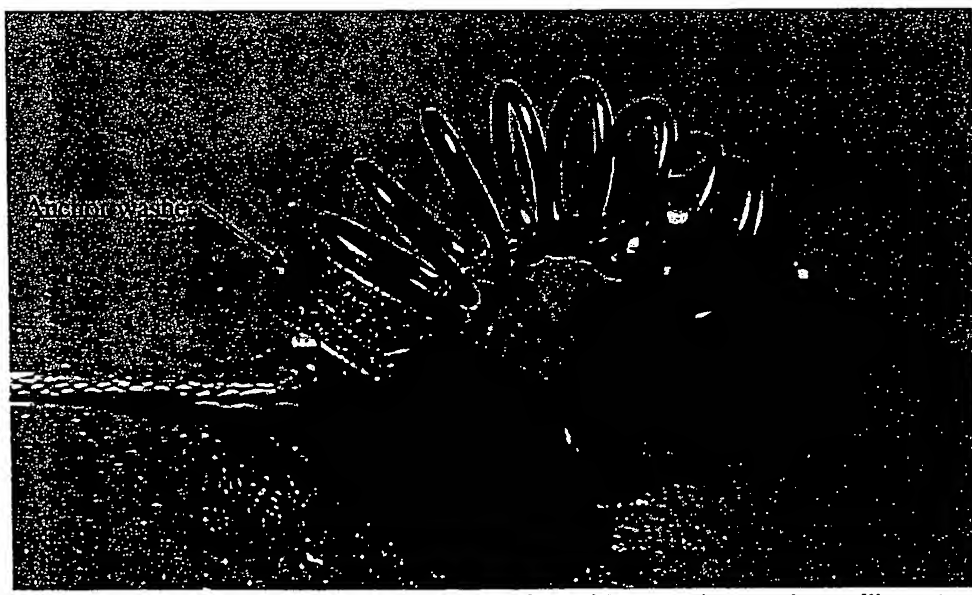


Figure 17: A .156" diameter compression spring with an anchor washer, still curves some with compression. The .156" diameter spring stores approximately 1.2 pounds with 1 centimeter of compression.

1/14/00

David H. Gy 1/14/00

READ & UNDERSTOOD - Diane Carter 1/17/00

COMPRESSION SPRING IN SERIES

Tether line compression spring in series

Figure 1: Compression spring with machined end caps in tension.

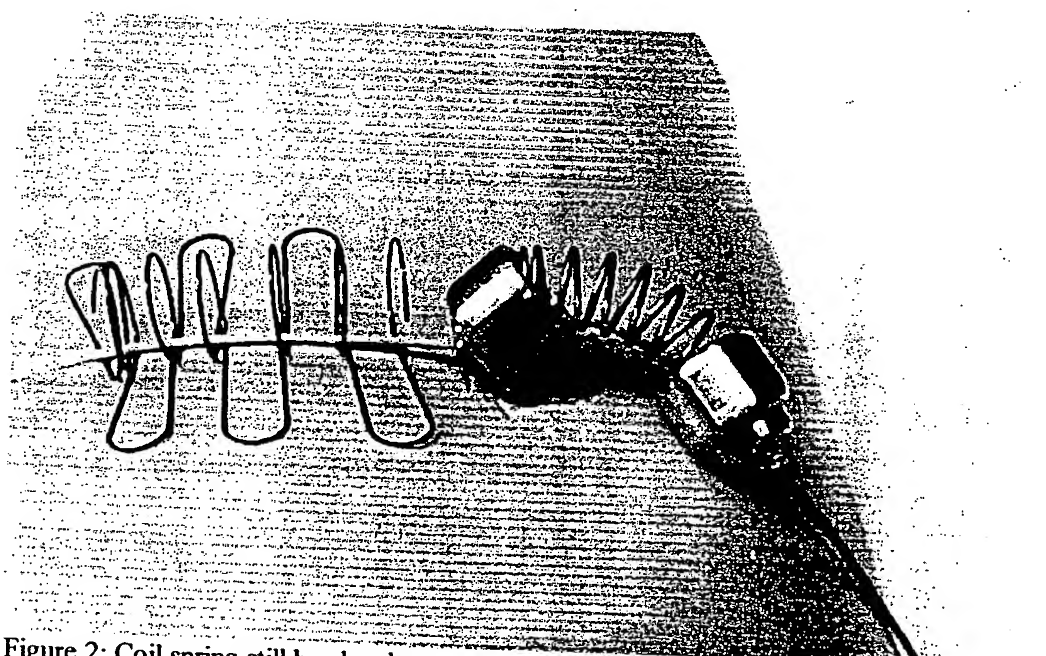


Figure 2: Coil spring still bends when compressed by tension in the tether line. Some type of telescoping shafts (like a shock absorber) may be needed to straighten movement of the spring.

1/24/00

READ
& UNDERSTOOD

2/21/00

RIGID RIGHT SIDE TUBE SUPPORT WITH CABLE ACTIVATION

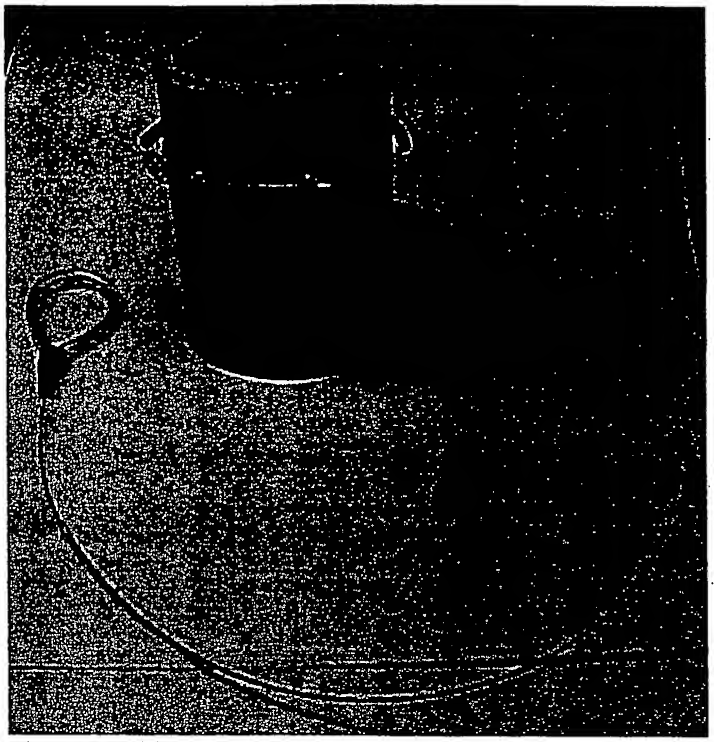


Figure 1: Nitinol wire tether line harness with rigid tube wall support, stand-offs and .042" diameter polyimide/stainless steel reinforced activation cable.

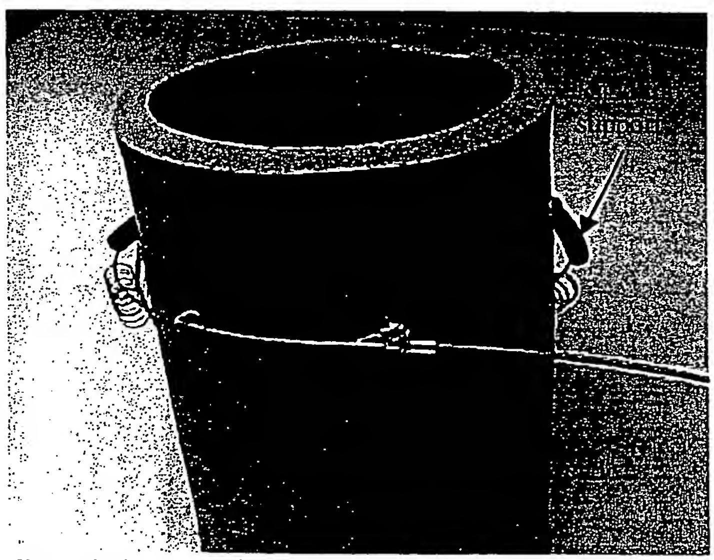


Figure 2: Harness with rigid support tube on the backside of the foam model.

1/24/00

READ + UNDERSTOOD

1/24/00

RIGID TUBE SUPPORT WITH FOAM MODEL CONT

Figure 3: Front view of harness in the tensioned state, pulling in the unsupported wall of the foam model.

Figure 4: Side view showing the rigid tube side staying more cylindrical and the harness side of the model being compressed.

1/24/00

READ & UNDERSTOOD

2/21/00

RIGID TUBE SUPPORT - CONT

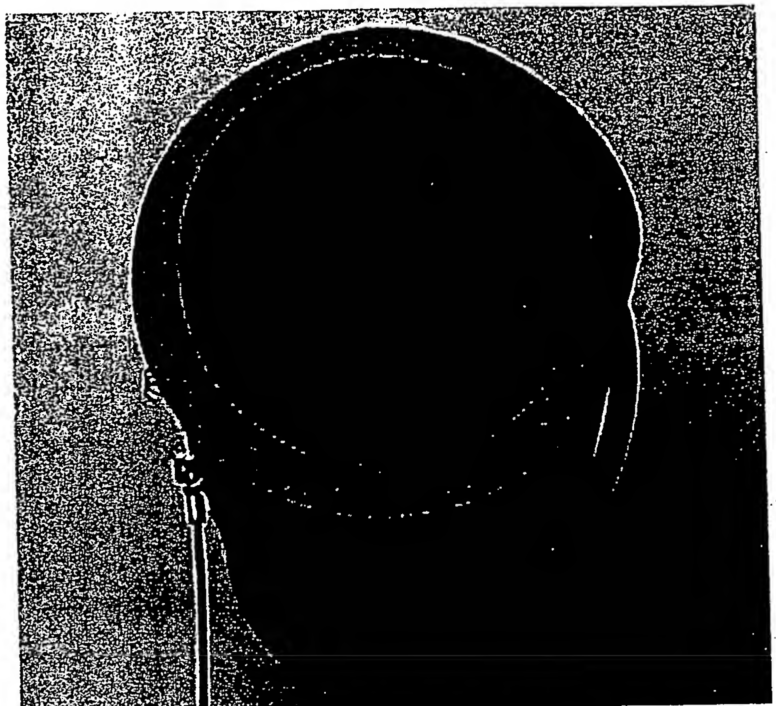


Figure 5: Top view showing cylindrically shaped model with relaxed harness.

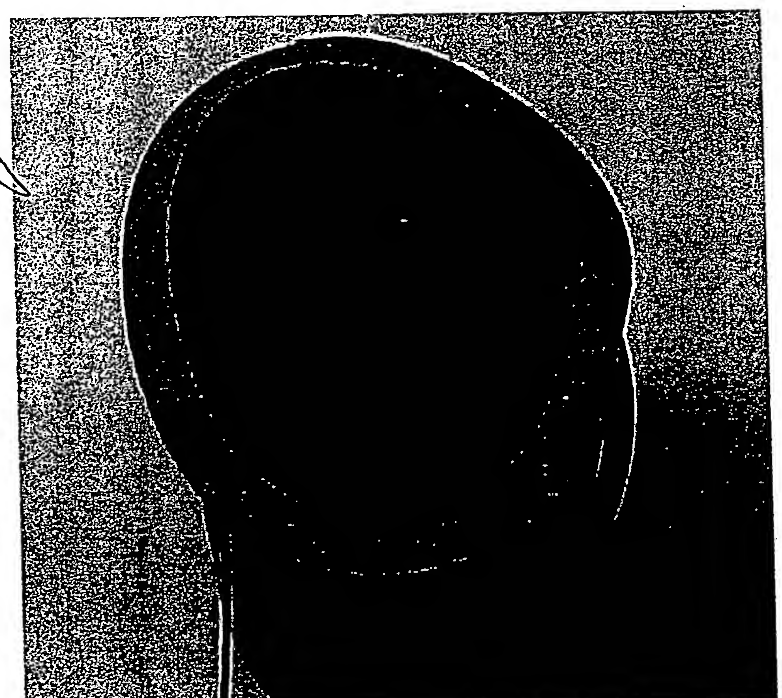


Figure 6: Illustrating more compression on the left side, while the rigid tube side stays more cylindrical and less compressed.

1/24/00

1/24/00

READ & UNDERSTOOD

2/21/00

DUAL LINE CENTER PULL CABLE

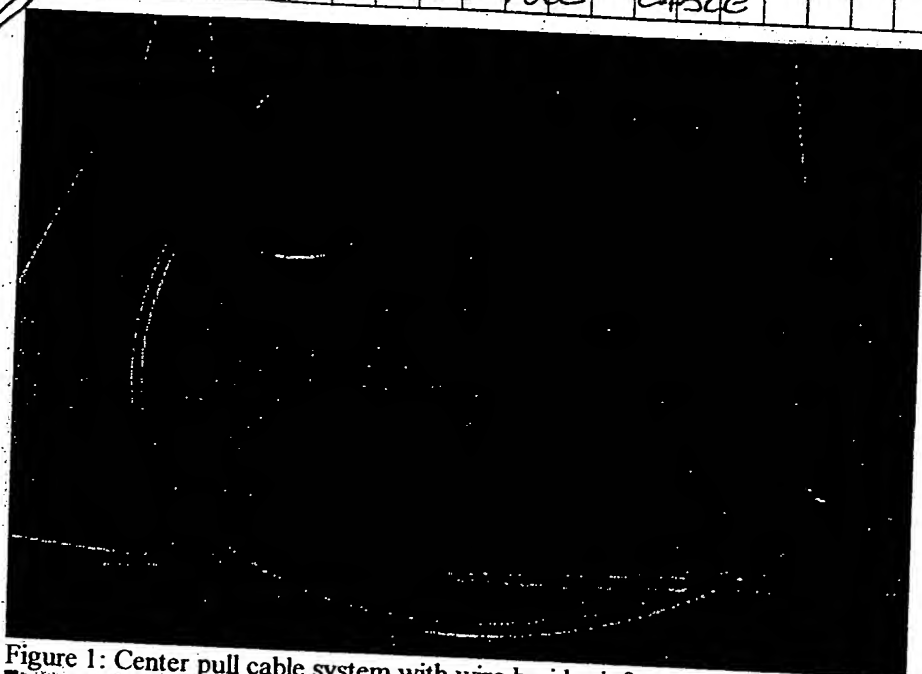


Figure 1: Center pull cable system with wire braid reinforced extruded housing.

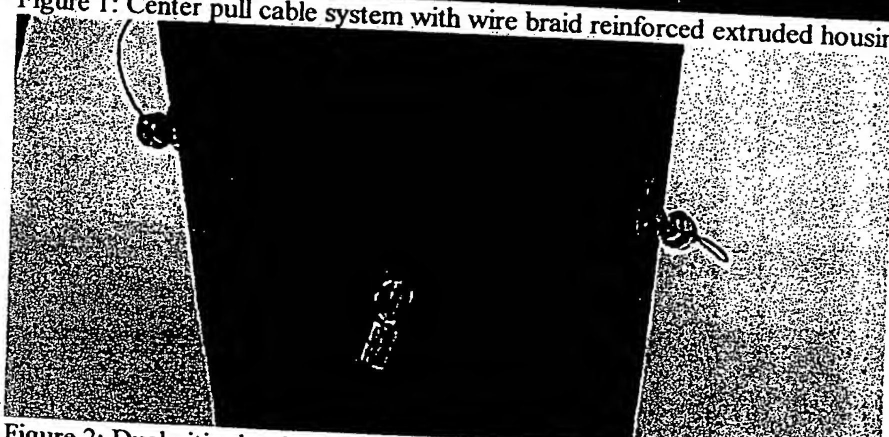


Figure 2: Dual nitinol tether line with end termination devices in slack condition.

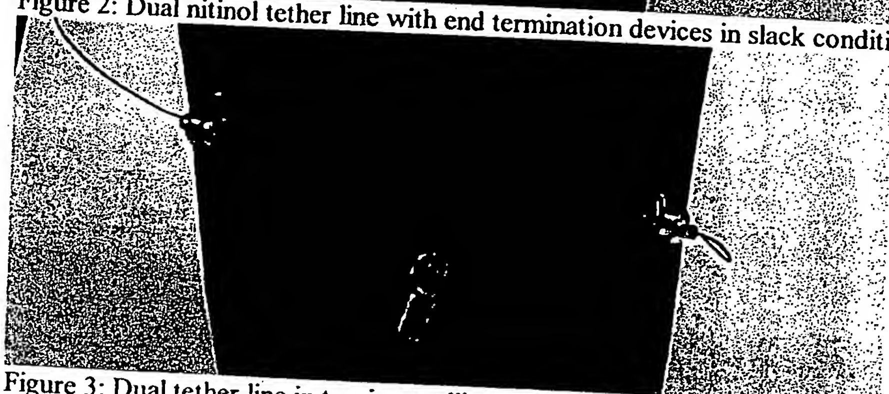


Figure 3: Dual tether line in tension, pulling in both ends at once.

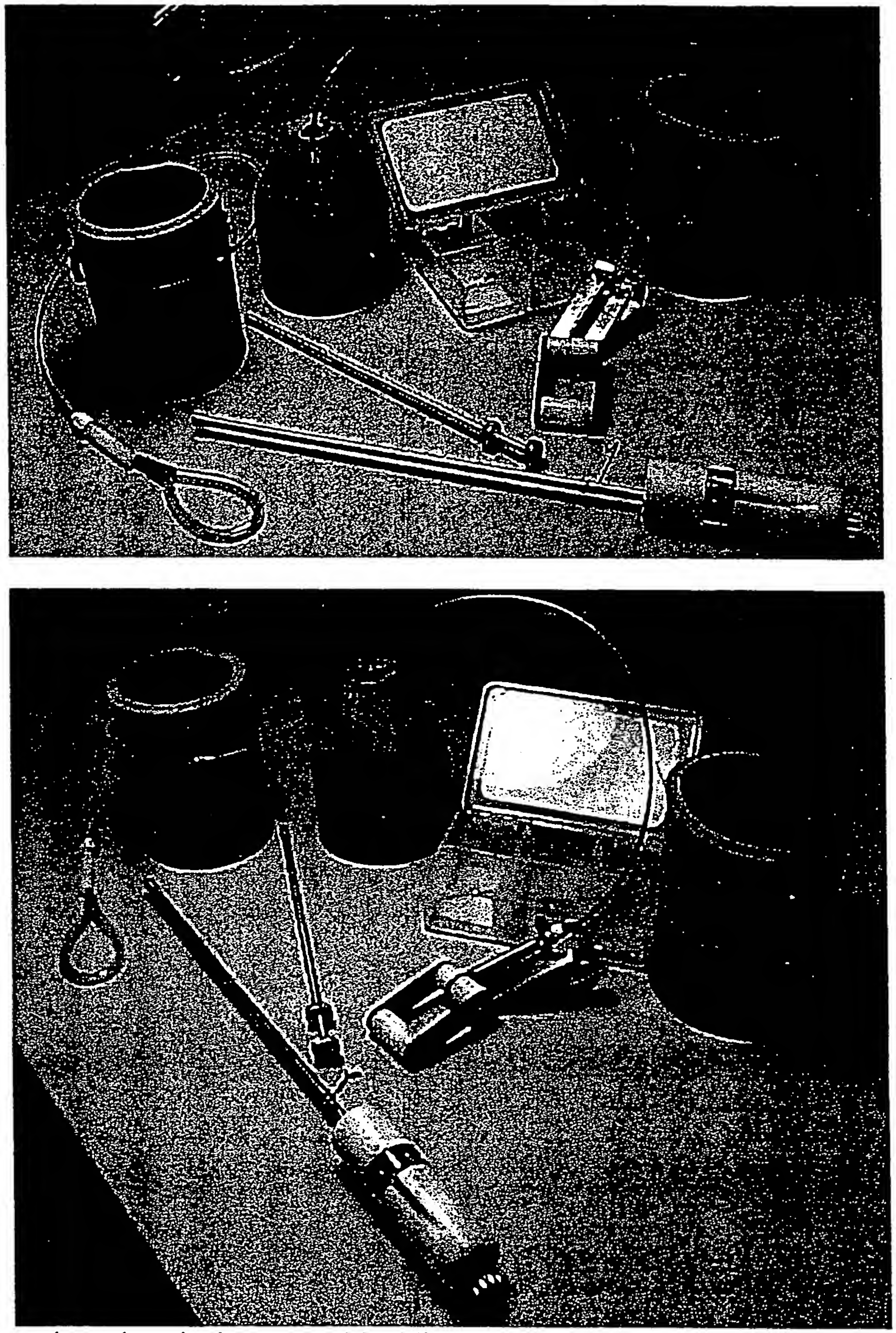
1/25/00

1/25/00

READ & UNDERSTOOD

2/21/00

DEMONSTRATION MODELS



Active and passive harness models, delivery systems and components shown to Dr. Ray Chiu on 1-31-00, Dr. James Magovern on 1-25-00 and Dr. Larry Stephenson on 1-24-00.

1/28/00

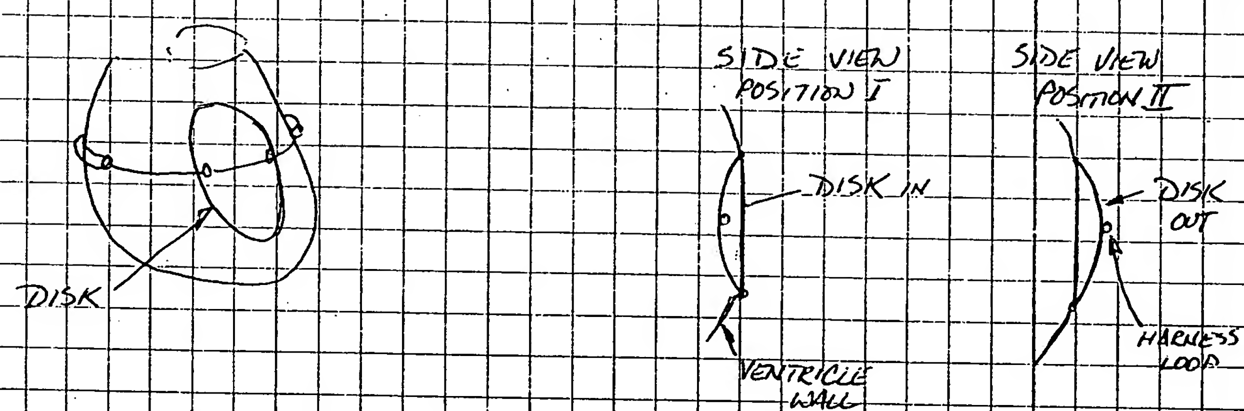
1/28/00

READ & UNDERSTOOD

2/21/00

BI-STABLE DISK TO ASSIST LEFT VENTRICULAR CONTRACTION

A BI-STABLE DOMED DISK MAY BE USED TO COMPRESS THE EPICARDIAL SURFACE OF THE LEFT VENTRICLE. THE BI-STABLE CHARACTERISTIC (OIL CAN EFFECT) WOULD USE A HARNESS TO COMPRESS THE DOMED DISK "OVER-CENTER", THEN THE ENERGY OF THE DISK WILL HELP COMPRESS THE OUTSIDE WALL OF THE LEFT VENTRICLE.



DURING DIASTOLIC FILLING, THE PRESSURE FROM THE VENTRICLE WALL DUE TO FILLING, WOULD PUSH THE DOMED DISK BACK OUT TO IT'S OUTWARD STABLE CONDITION. THE HARNESS WOULD PULL IN TENSION AGAIN TO REPEAT THE CYCLE.

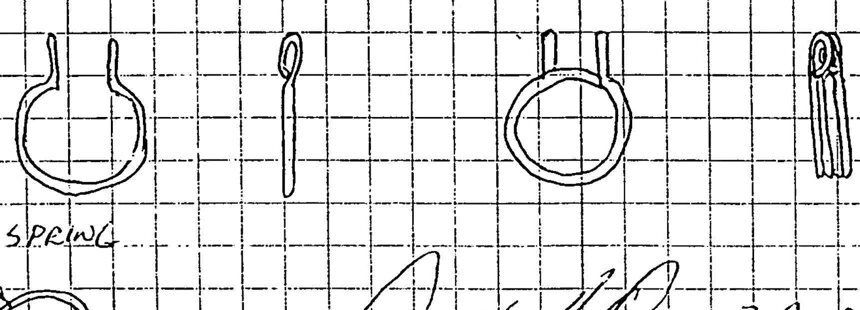
[signature] 2-7-00

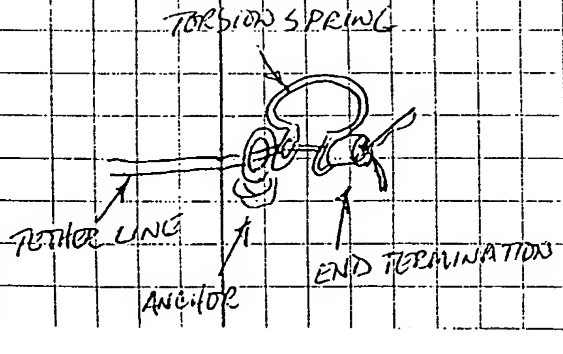
READ & UNDERSTOOD

[signature] 2/21/00

TORSION SPRING IN SERIES WITH TETHERLINE

THE COMPRESSION SPRINGS USED IN SERIES WITH THE TETHER LINE TENDED TO CURL AND BUCKLE WITHOUT SUPPORT. WHEN SUPPORT GUIDES AND END CAPS WERE ADDED, THE SPRING ASSEMBLY BECAME BULKY (SEE PAGE 69). SMALLER DIAMETER SPRINGS AND GUIDES PLACED ON THE OUTSIDE OF THE SPRING WILL REDUCE THE SIZE, BUT ANOTHER CONCEPT WOULD BE TO USE A TORSION SPRING. THE TORSION SPRING WILL POTENTIALLY SIT MUCH FLATTER AND HAVE A LOWER FUNCTIONAL PROFILE. THE STRENGTH OF THE SPRING CAN BE VARIED BY THE WIRE DIAMETER, DIAMETER OF THE COILS, OR NUMBER OF COILS (TURNS)





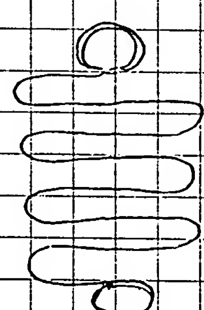
Daniel [signature] 2-9-00

READ & UNDERSTOOD

[signature] 2/24/00

LOWER PROFILE STAND-OFF

THE TETHER LINE GUIDE RINGS ARE CURRENTLY LARGE ENOUGH IN DIAMETER TO SLIDE OVER THE .186" SHAFT OF THE ANCHOR DELIVERY SYSTEM. THIS ~.190" DIAMETER HAS THE POTENTIAL TO INTERFERE WITH THE PERICARDIUM, OR CHEST WALL AND COULD ADVERSLY EFFECT THE MOTION OF THE HEART. BY ELIMINATING THE GUIDE RINGS IN THE MIDDLE (BODY) OF THE STAND-OFFS AND TILTING THE END GUIDE RINGS DOWN AT AN ANGLE, IT SHOULD REDUCE THE FINAL PROFILE (HEIGHT) OF THE PART. THE ANGLED, OR FLAT END RINGS CAN BE TILTED UP TO SLIDE OVER THE SHAFT OF THE ANCHOR DELIVERY SYSTEM, TO BE PUSHED OFF ONE AT A TIME

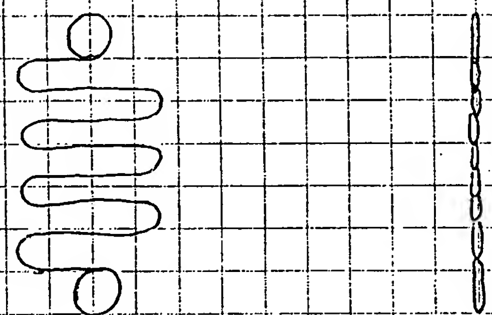


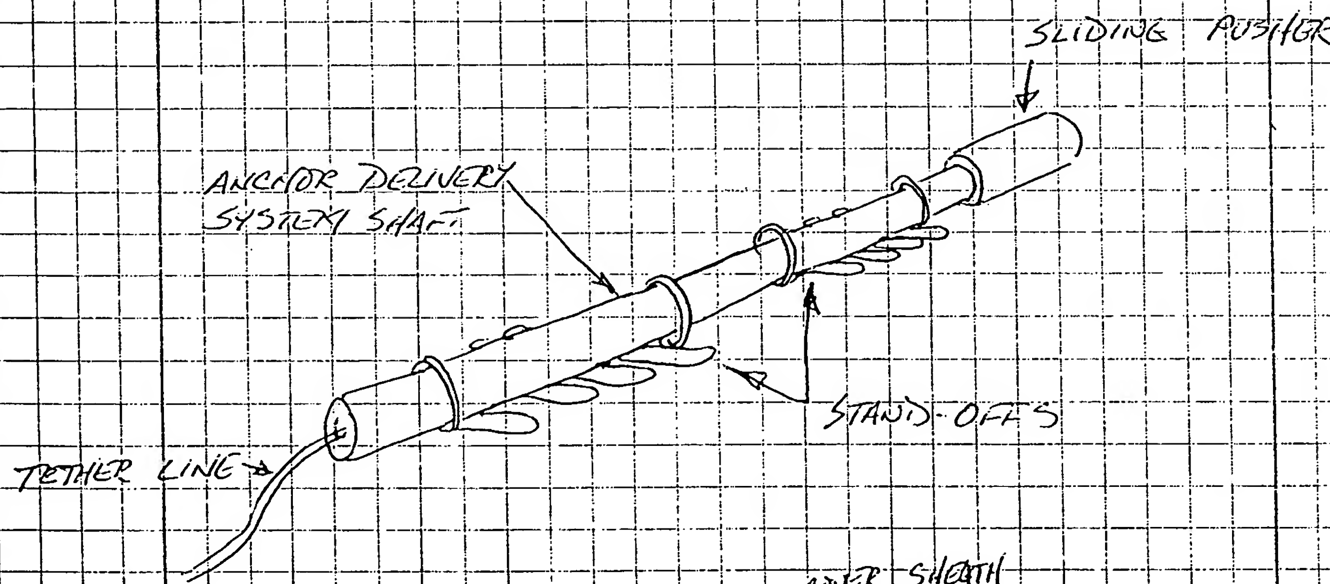
[signature] 2-10-00

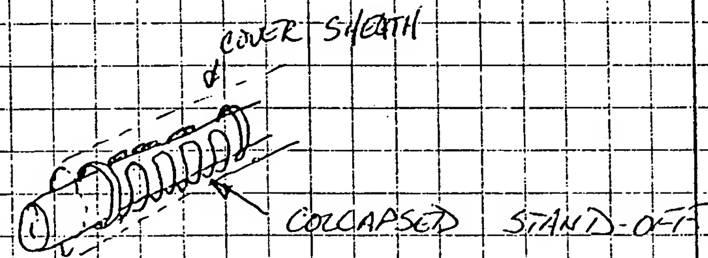
READ & UNDERSTOOD [signature] 2/10/00

LOWER PROFILE STANDOFF - CONTINUED

THE END RINGS MAY ALSO BE FORMED FLAT INSTEAD OF ANGLED.



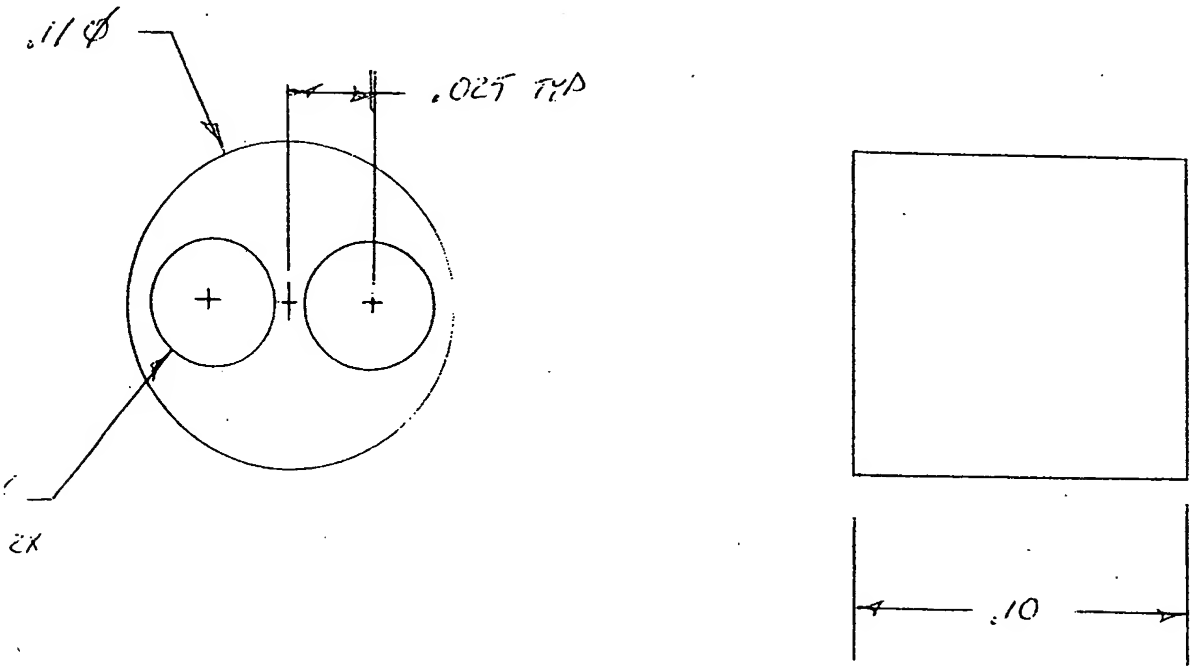




[signature] 2-10-00

READ & UNDERSTOOD [signature] 2/21/00

TETHERLINE END TERMINATION BUTTON



TWO HOLE TERMINATION BUTTON

MATERIAL: BRASS

TOLERANCES: XX ± .01
XXX ± .003

[signature] 2-9-00

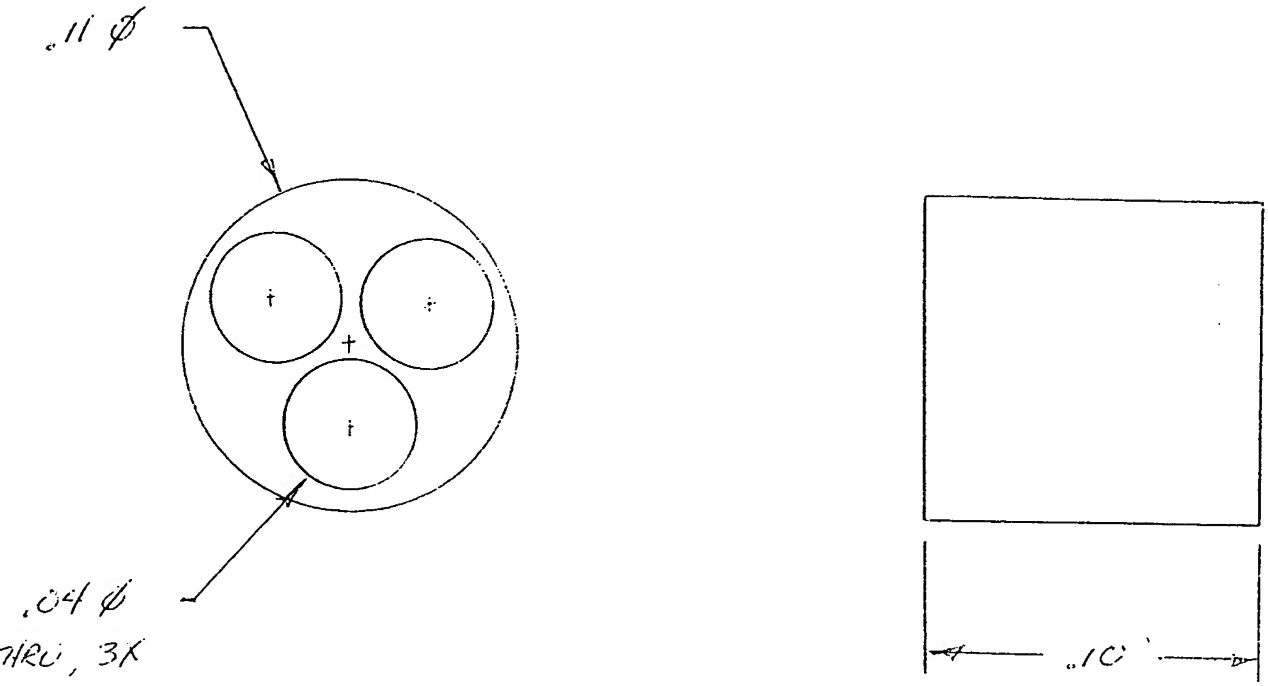
TWO HOLE TERMINATION BUTTON ALLOWS TETHER LINE TO BE THREADED THROUGH THE TWO HOLES, THEN SECURED WITH SQUARE KNOTS.

[signature]

2-10-00

READ
UNDERSTOOD [signature] 2/24/00

THREE HOLE TERMINATION BUTTON



HOLE PATTERN, .027 CENTERS, 120° APART

THREE HOLE TERMINATION BUTTON
MATERIAL: BRASS
TOLERANCES: XX= ± .01
XXX= ± .003

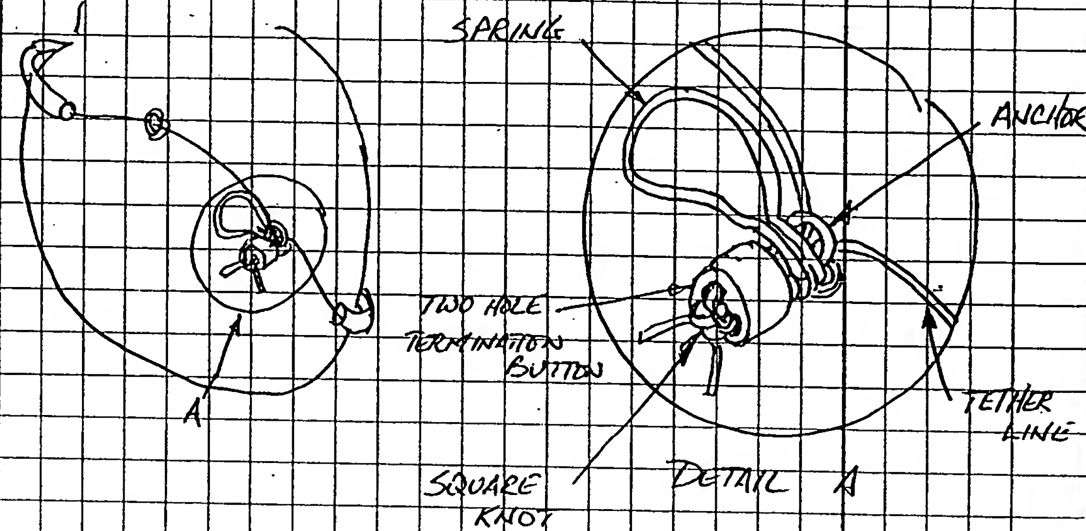
2-9-00

A THREE HOLE TERMINATION BUTTON MAY BE USED TO KEEP THE TETHER LINE COMPRESSION SPRING, OR TETHER LINE TORSION SPRING IN LINE WITH THE HARNESS WHEN USING THE RIGID SUPPORT TUBE, RATHER THAN AT 90°.

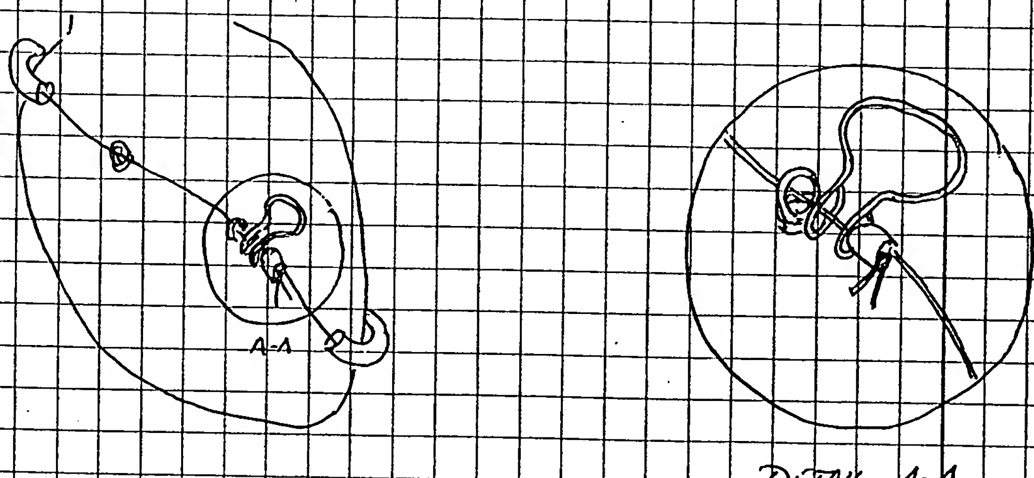
2-10-00 READ + UNDERSTOOD 2/24/00

2/10/00

THREE HOLE TERMINATION BUTTON CONTINUED



TWO HOLE TERMINATION BUTTON



DETAIL A-A

THREE HOLE TERMINATION BUTTON

THE TWO HOLE BUTTON COULD ALSO BE USED IN-LINE IF A DOUBLE TETHER LINE IS USED AND STARTED AT THE SAME ANCHOR AS IT TERMINATES, OR AT THE END OF THE RIGID TUBE SUPPORT.

2-10-00

READ & UNDERSTOOD

2/21/00

TORSION SPRINGS IN SERIES WITH TETHER LINE

Torsion springs for partial harness assist.

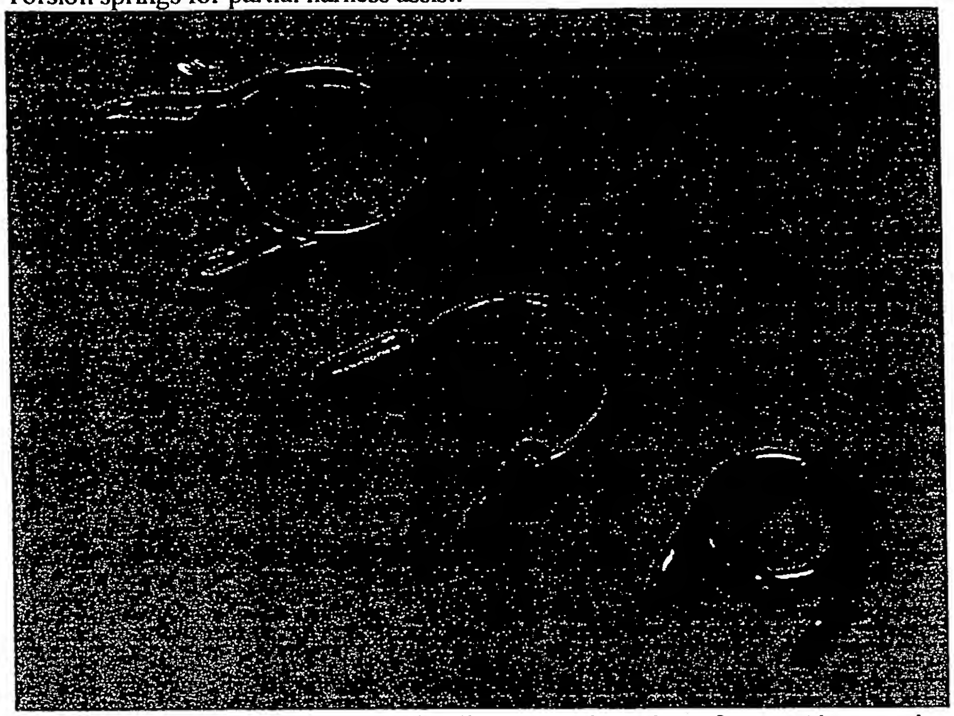


Figure 1: Spring forces vary with wire diameter and number of turns. Above springs Have 0.5lb, 1.5-2.0lb and 4.5lb from left to right (.026" and .036" wire).

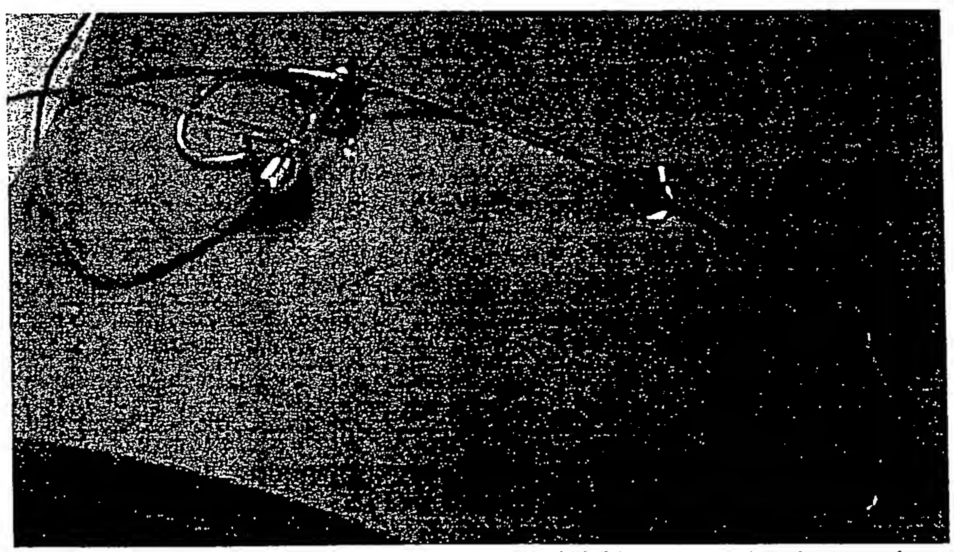


Figure 2: Tether line routed through anchors and rigid support tube, then terminated with a torsion spring and two line termination button.

[signature] 4/10/00

READ & UNDERSTOOD [signature] 9/21/00

TORSION SPRINGS IN SERIES CONTINUED.

2/10/00

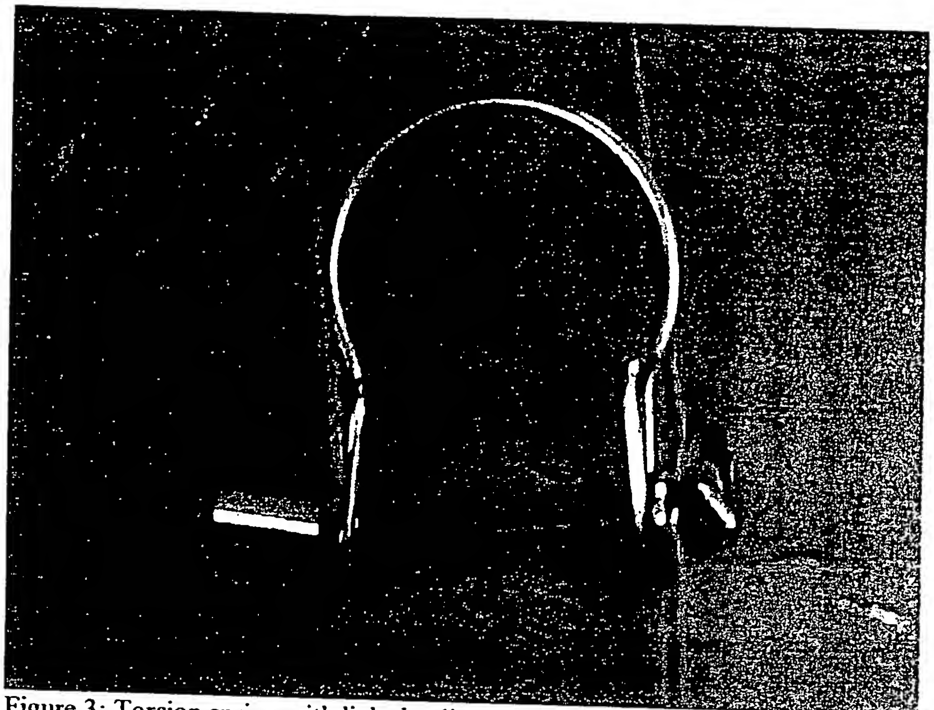


Figure 3: Torsion spring with light loading, prior to slack in the tether line.

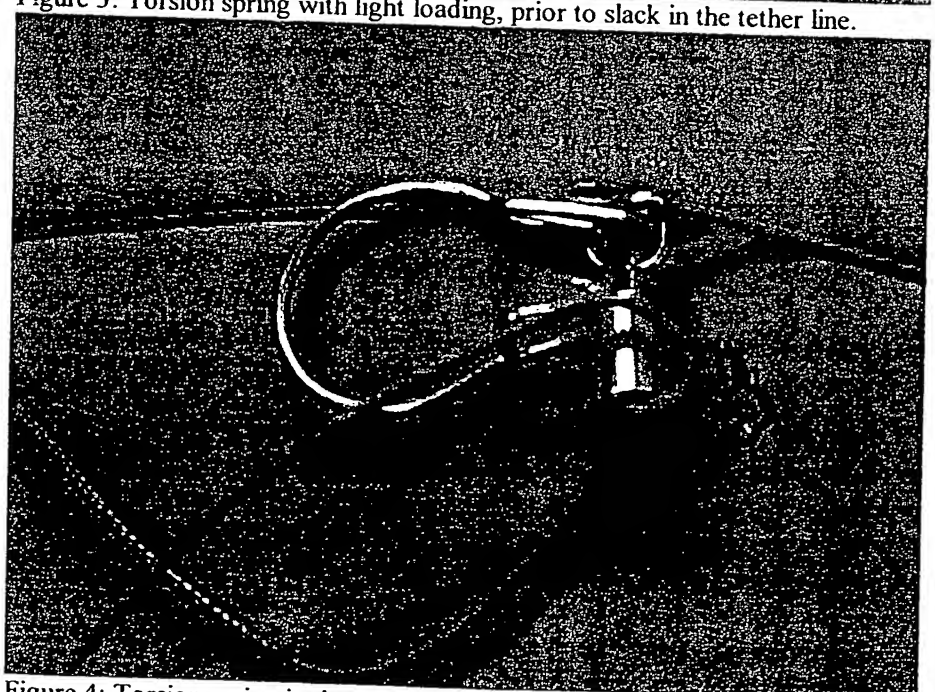


Figure 4: Torsion spring in the compressed condition, almost fully loaded.

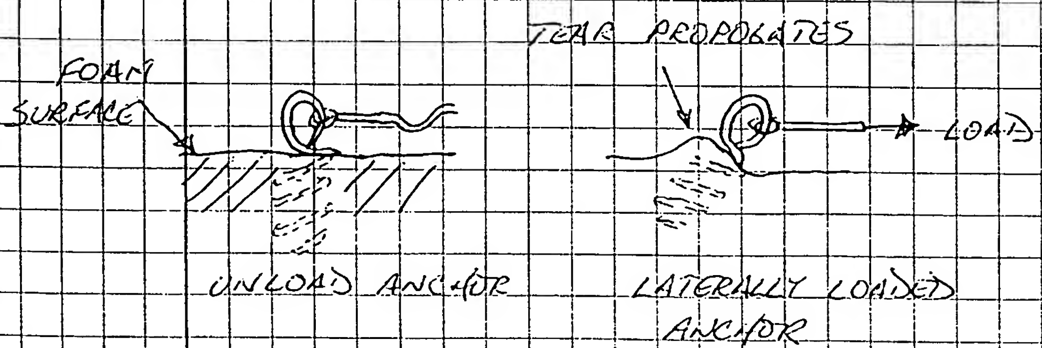
2/10/00

READ
+ UNDERSTOOD

2/24/00

ANGLED END ANCHORS

TO REDUCE THE LATERAL STRESSES INDUCED ON THE MYOCARDIUM BY THE LATERAL LOADING OF THE PASSIVE HARNESS ANCHORS (ESPECIALLY THE END ANCHORS), THE COIL ANCHORS MAY BE DRIVEN INTO THE TISSUE AT AN ANGLE, TO COUNTER ACT THE LATERAL LOAD. IT HAS BEEN NOTED WHEN LATERAL LOAD IS APPLIED TO A COILED ANCHOR DRIVEN STRAIGHT INTO (PERPENDICULAR TO THE SURFACE) IN A FOAM MODEL, THE SURFACE OF THE FOAM WILL EVENTUALLY TEAR AND BECOME COMPROMISED. BY PLACING THE ANCHORS AT A 45° ANGLE, OR GREATER, THE LATERAL LOAD AT THE SURFACE, MAY BE REDUCED.

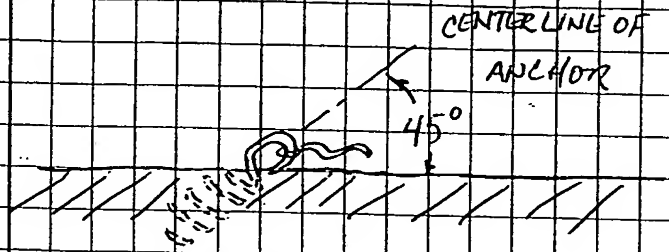


2-12-00

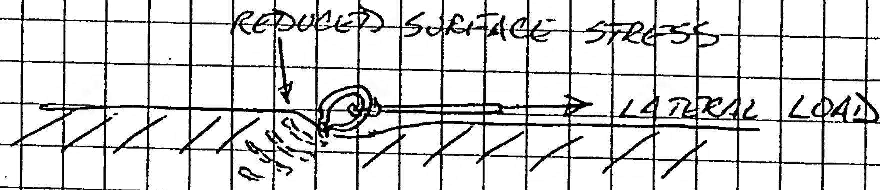
READ & UNDERSTOOD

2/21/0

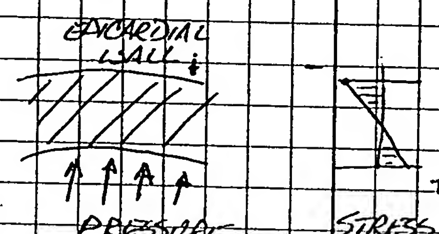
ANGLED ANCHOR CONTINUED



UNLOADED
ANGLED ANCHOR



LESS MOMENT SHOULD BE CREATED AT THE SURFACE, SINCE THE ANCHOR DOES NOT HAVE TO TILT AS MUCH FROM THE NEUTRAL PERPENDICULAR ORIENTATION. THIS MAY BE SIGNIFICANT, SINCE THE SURFACE STRESSES ON THE EPICARDIAL WALL OF THE LEFT VENTRICLE HAVE THE HIGHEST TENSILE STRESSES WHEN PRESSURIZED.

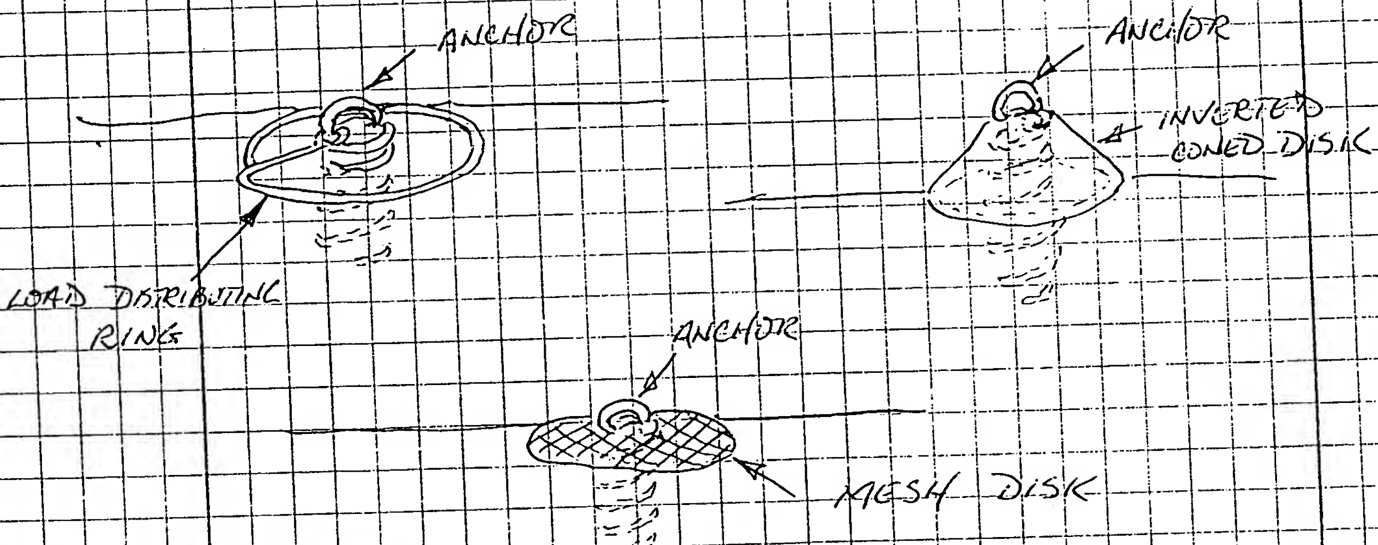


[signature] 2/12/00

READ + UNDERSTOOD [signature] 2/14/00

STRAIN RELIEF CAP FOR ANCHORS

ANOTHER METHOD TO REDUCE STRAIN AT THE EPICARDIAL SURFACE IS TO INCREASE THE CONTACT SURFACE OF THE ANCHOR. THIS INCREASED SURFACE AREA CAN BE ACCOMPLISHED BY A WIRE LOOP WITH A SIGNIFICANTLY LARGER DIAMETER THAN THE ANCHOR, A SEPERATE CONICAL, OR COVEX DISK, OR A MESH SURFACE TO ALLOW FIBROSIS TO OCCUR THROUGHOUT THE MESH FOR LONG TERM STABILITY AND SECURITY.



THE THEORY OF THESE DISKS, OR RINGS IS TO STABILIZE AND SUPPORT THE EPICARDIAL SURFACE AND REDUCE STRAIN WITH LATERAL LOADING TO THE ANCHORS.

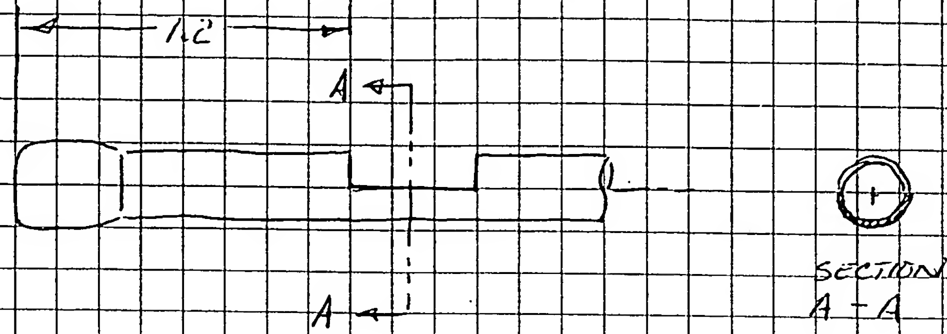
2-14-00 READ + UNDERSTOOD 2/21/00

MODIFIED PEACEMAKER

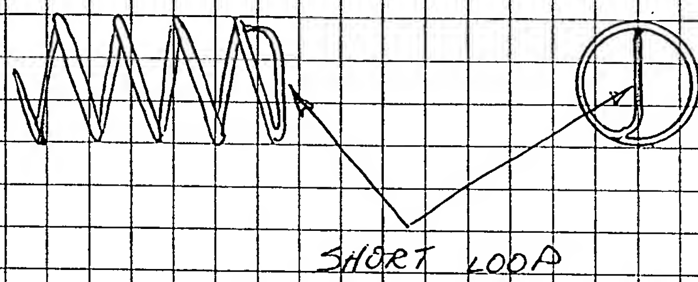
THE MULTI-ANCHOR DELIVERY SYSTEM MAY BE MODIFIED TO FUNCTION AS A SINGLE SHOT DELIVERY SYSTEM THAT WILL NOT REQUIRE THE FULL RETRACTION AND SEPARATION OF THE DRIVE ROD FROM THE HOUSING/BODY OF THE DELIVERY MECHANISM. A SLOT LONG AND WIDE ENOUGH TO ACCOMMODATE AN ANCHOR CAN BE MACHINED, OR GROUND INTO THE DELIVERY TUBE, PROXIMAL OF THE THREADED TIP OF THE DELIVERY TUBE. TO REDUCE DELIVERED PROFILE OF THE CARDIAC HARNESS, THE LOOP OF THE ANCHOR MAY BE SHORTENED IN HEIGHT TO WHERE THE TETHER LINE LOOP WILL ONLY BE AS TALL (THE GAP) AS THE TETHER LINE IS THICK. TO DRIVE THE LOWER PROFILE ANCHOR, THE DRIVE MECHANISM MAY HAVE TO BE MODIFIED, BY HAVING PROTRUDING PINS RATHER THAN A SLOT MACHINED INTO THE END OF THE DRIVE ROD.

[signature] 2-16-00 READ & UNDERSTOOD [signature] 2/21/00

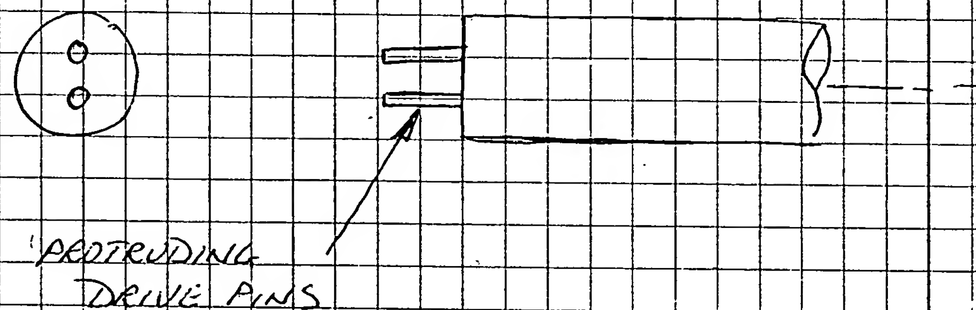
MODIFIED PEACEMAKER - CONTINUED



SLOT IN DELIVERY TUBE



MODIFIED LOW PROFILE ANCHOR



MODIFIED ANCHOR DELIVERY DRIVE MECHANISM

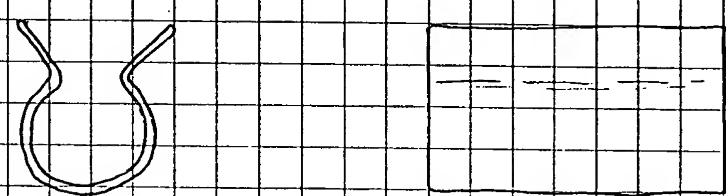
2-16-00

READ
+
UNDERSTOOD

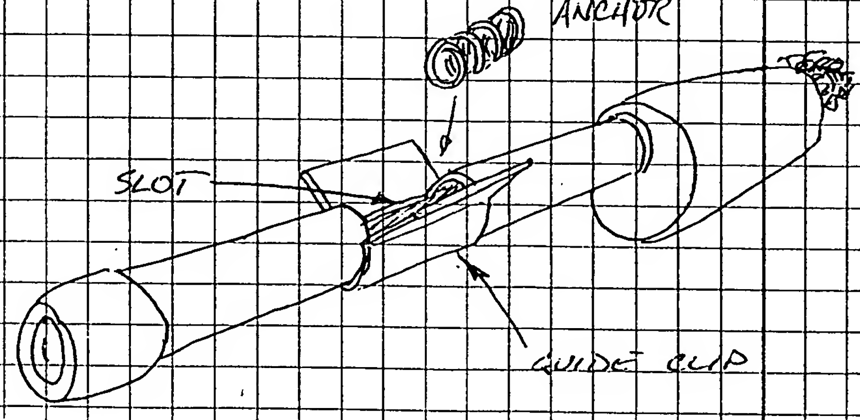
2/2[illegible]/00

MODIFIED PEACEMAKER CONTINUED

TO HELP CENTER AND GUIDE THE MODIFIED ANCHORS INTO THE SIDE SLOT OF THE DELIVERY TUBE, A SHEET METAL GUIDE, OR CLIP CAN BE MADE TO SLIDE OVER THE DELIVERY TUBE. THE CLIP CAN BE FLARED AT THE OPEN END TO HELP "FUNNEL" THE ANCHORS INTO THE SLOT.



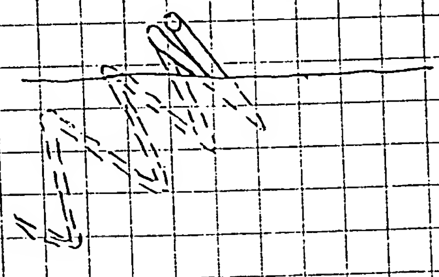
GUIDE CLIP

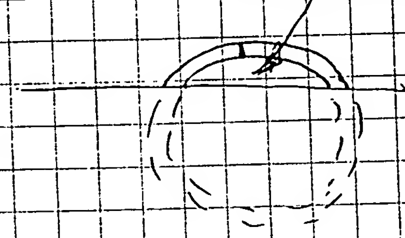


2-16-00 READ & UNDERSTOOD 2/21/00

ANGLED END ANCHORS

A METHOD FOR INSERTING THE ANCHORS AT AN ANGLE WOULD BE TO SET THE DELIVERY DEVICE NORMAL TO THE EPICARDIAL SURFACE FOR ONE TO TWO REVOLUTIONS OF THE ANCHOR/DRIVE MECHANISM, THEN TILT THE DELIVERY DEVICE AT A 30°-~~40°~~ DHO 2-16-00 45° ANGLE AND COMPLETE THE INSERTION AT AN ANGLE. THIS METHOD SHOULD ALLOW THE ANCHOR TO START INTO THE TISSUE, BUT THEN BE DRIVEN FURTHER INTO THE TISSUE AT AN ANGLE. ANGLED SINGLE SHOT (CLOSED LOOP) ANCHORS MAY LEAVE MORE OF A TETHER LINE LOOP EXPOSED WHEN INSERTED AT AN ANGLE.





2-16-00

READ + UNDERSTOOD 2/21/00

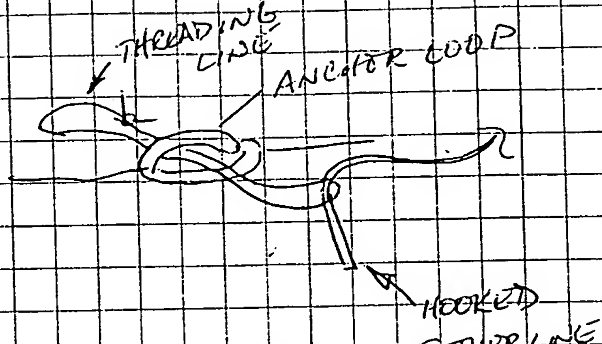
ALTERNATE ANCHOR TERMINATION

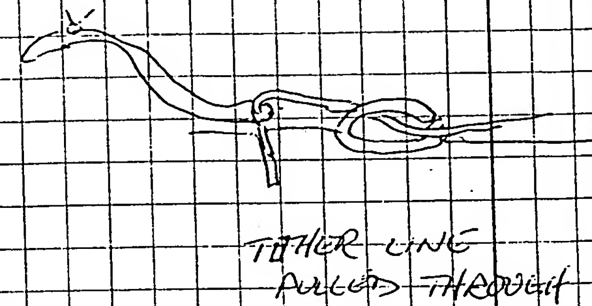
IF THE ANCHORS ARE INSERTED INTO THE MYOCARDIUM PRIOR TO THE TETHER LINE BEING ATTACHED, THEY CAN BE THEADED AFTER INSERTION, OR THE ANCHOR TERMINATION MAY ALLOW "QUICK", ONE WAY CAPTURE OF THE TETHER LINE. WITH A CLOSED LOOP, A LARGE LOOPED "THREADER" LINE MAY BE LEFT IN THE ANCHOR LOOP AFTER INSERTION AND USED TO PULL THROUGH THE TETHER LINE. WITH AN OPEN LOOP, THERE MAY BE A SPRING FIT, OR TORTUOUS PATH TO ALLOW THE TETHER LINE TO SLIP IN, BUT NOT SLIP OUT. A DEFORMABLE SECONDARY PIECE MAY BE ATTACHED TO THE ANCHOR COIL TO ALLOW A TYPE OF SNAP FIT TO CAPTURE THE TETHER LINE. THIS FEATURE MAY BE PHOTO ETCHED, OR LASER CUT FROM SHEET METAL TO VARY THE THICKNESS OF SPECIFIC SECTIONS TO ENHANCE THE SNAP FIT FEATURES.

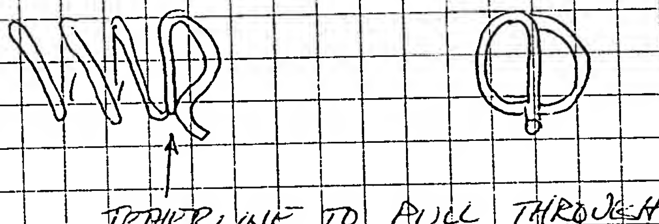
[signature] 2-16-00

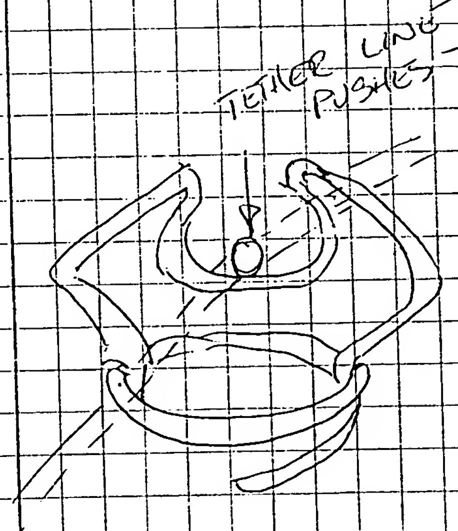
READ
✓ UNDERSTOOD [signature] 2/24/00

ALTERNATE ANCHOR TERMINATION CONTINUED

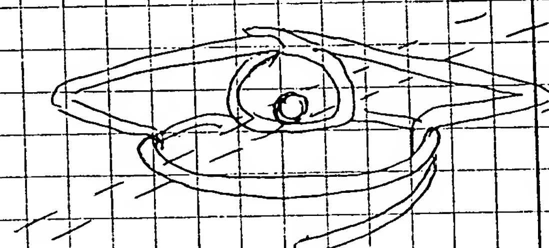








OPEN POSITION



CLOSED POSITION

2-16-00

READ & UNDERSTOOD 2/21/00

LOW PROFILE ANCHORS, STANDOFF AND SPRING

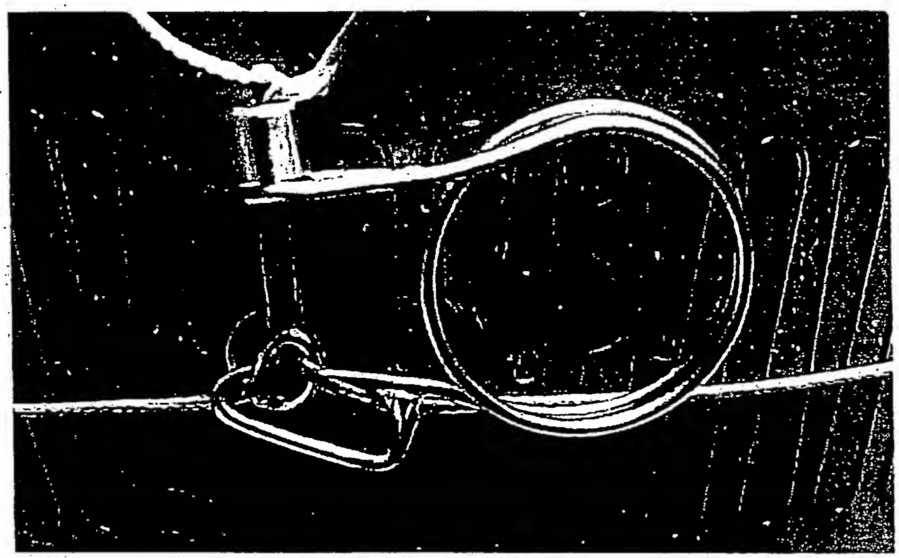


Figure 1: Torsion termination spring with single tether line and termination button.

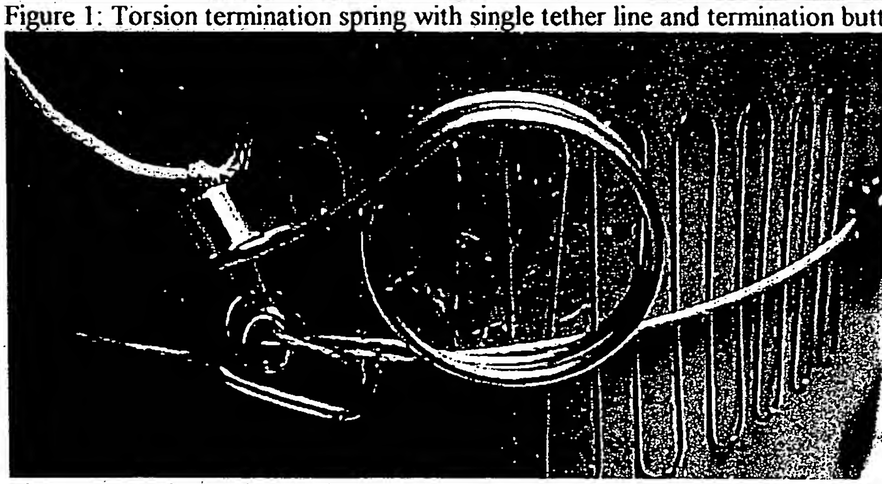


Figure 2: Torsion spring in higher tension.

THE LOWER PROFILE ANCHORS, STAND OFFS AND TORSION SPRINGS SIGNIFICANTLY REDUCE THE HEIGHT OF THE PASSIVE, SPRING ASSISTED HARNESS

2/23/00 READ UNDERSTOOD 3/22/00

LOW PROFILE HARNESS - CONT

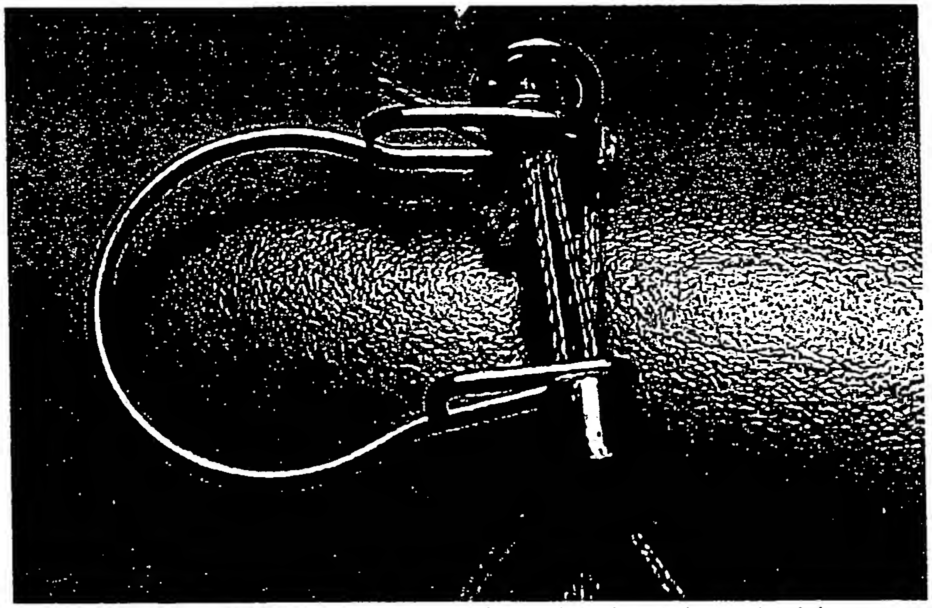


Figure 3: Torsion spring with dual tether line and anchor point on back bar.

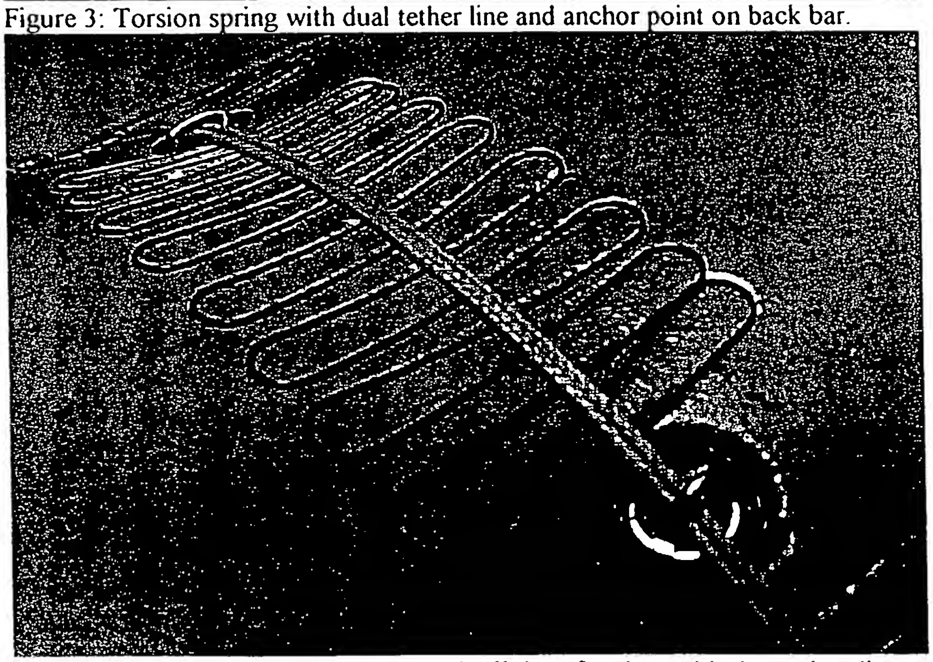


Figure 4: Low profile anchors and stand-offs interfere less with the pericardium.

DHC 2/25/00

ANCHOR POINT SOLDERED TO THE BACK BAR ALLOWS FOR DUAL TETHER LINE.

2/23/00 READ & UNDERSTOOD 3/29/00

LOW PROFILE HARNESS CONT.

DHO 2/23/00

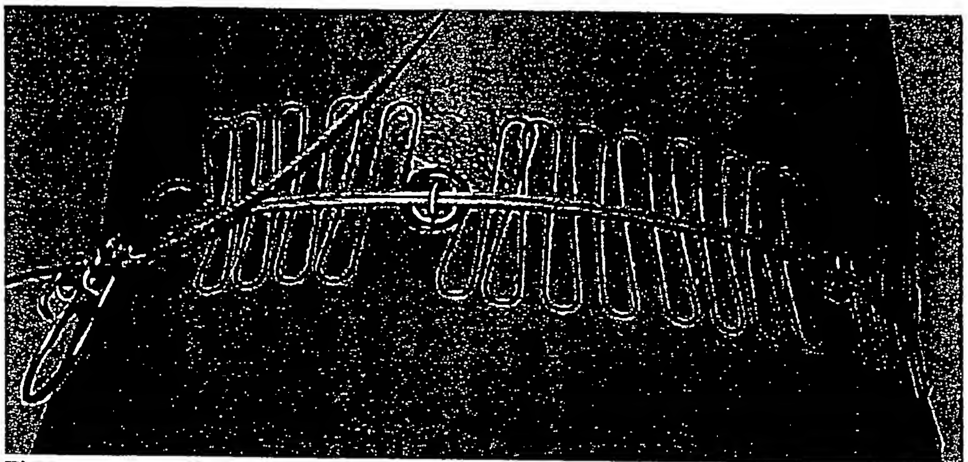


Figure 5: Dual tether line harness with low profile anchors, spring and stand-offs.

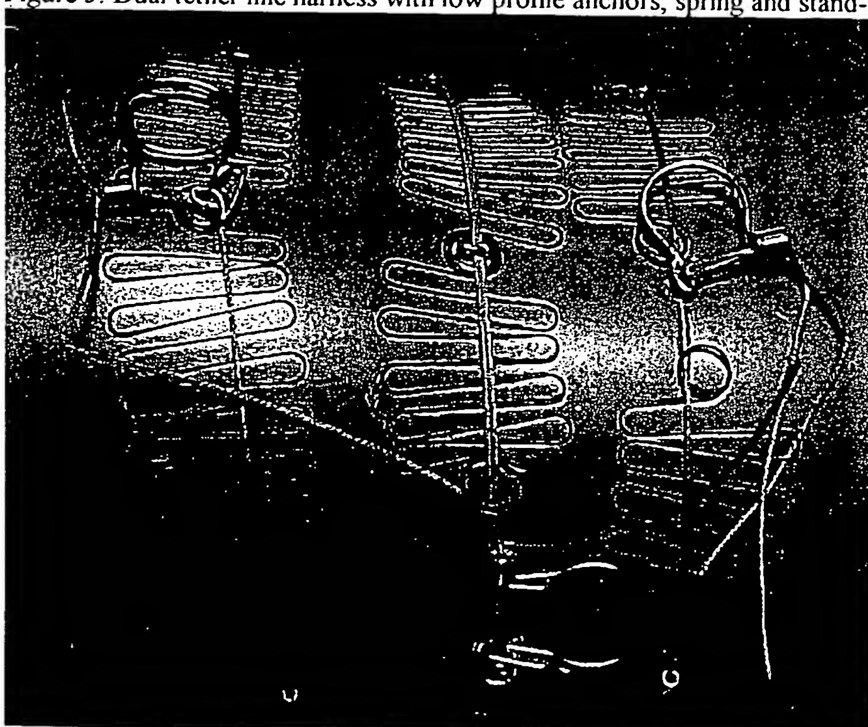


Figure 6: Three different configurations of tether lines, torsions springs, back bars and stand-offs.

END STAND-OFF LOOPS FIT OVER ANCHORS TO KEEP THEIR POSITION.

2/23/00

READ & UNDERSTOOD 3/24/00

MODIFIED ANCHOR DELIVERY SYSTEM (LOW PROFILE)

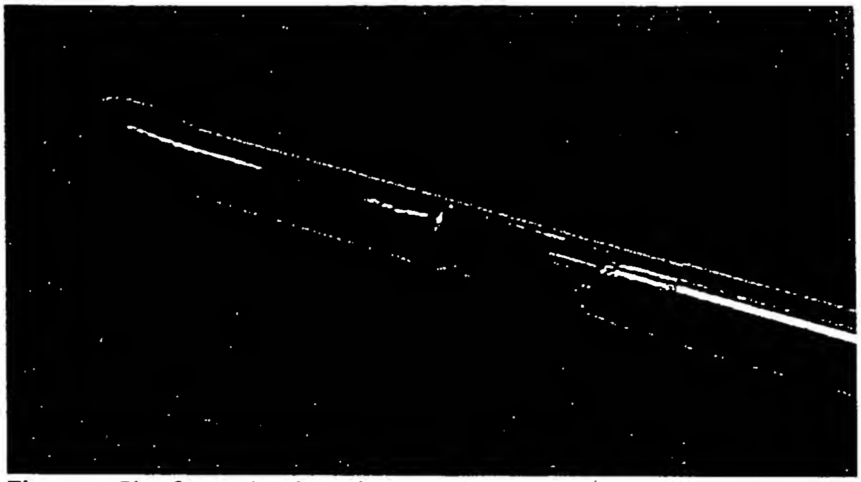


Figure 1: Slot for anchor insertion and pins for low profile anchor drive.

DHO 2/23/00

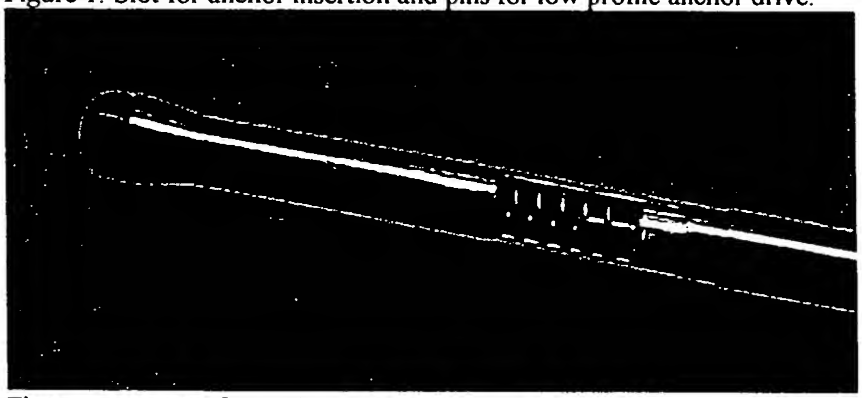


Figure 2: Low profile anchor engaged by drive pins.

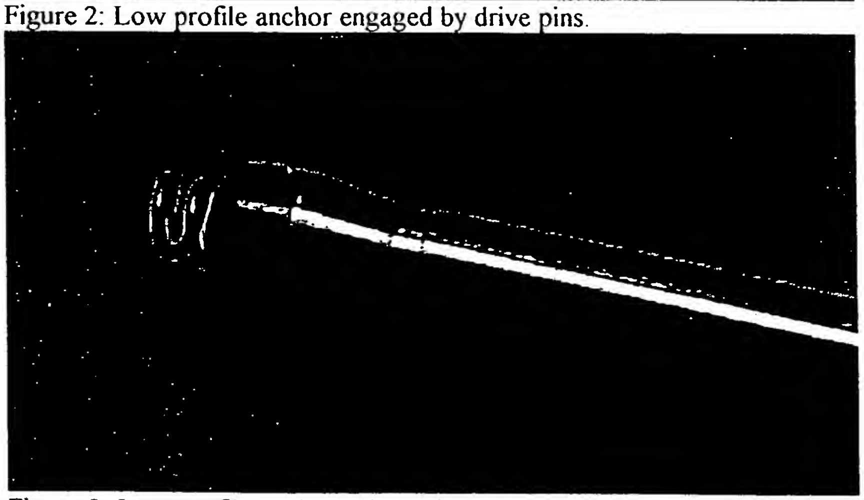


Figure 3: Low profile anchor being driven from delivery device. Note, sleeve is covering the slot.

2/23/00

Read & Understood

3/24/00

LOW PROFILE ANCHORS AND DELIVERY CONT

2/23/00

Figure 4: Low profile anchor being driven into foam model.

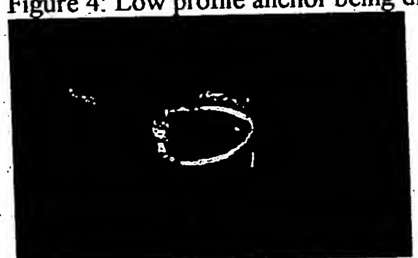


Figure 5: Low profile anchor in foam model.

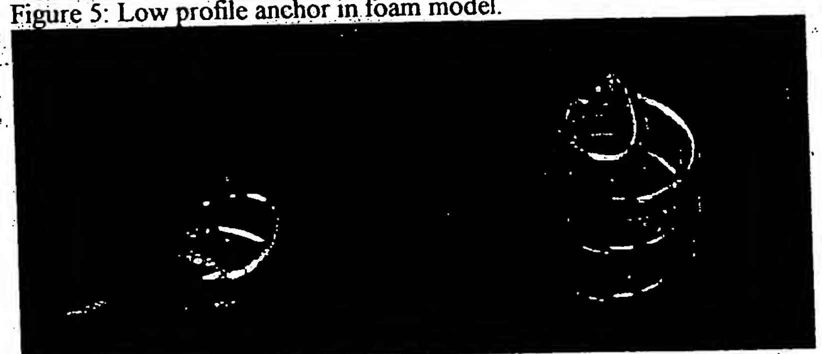


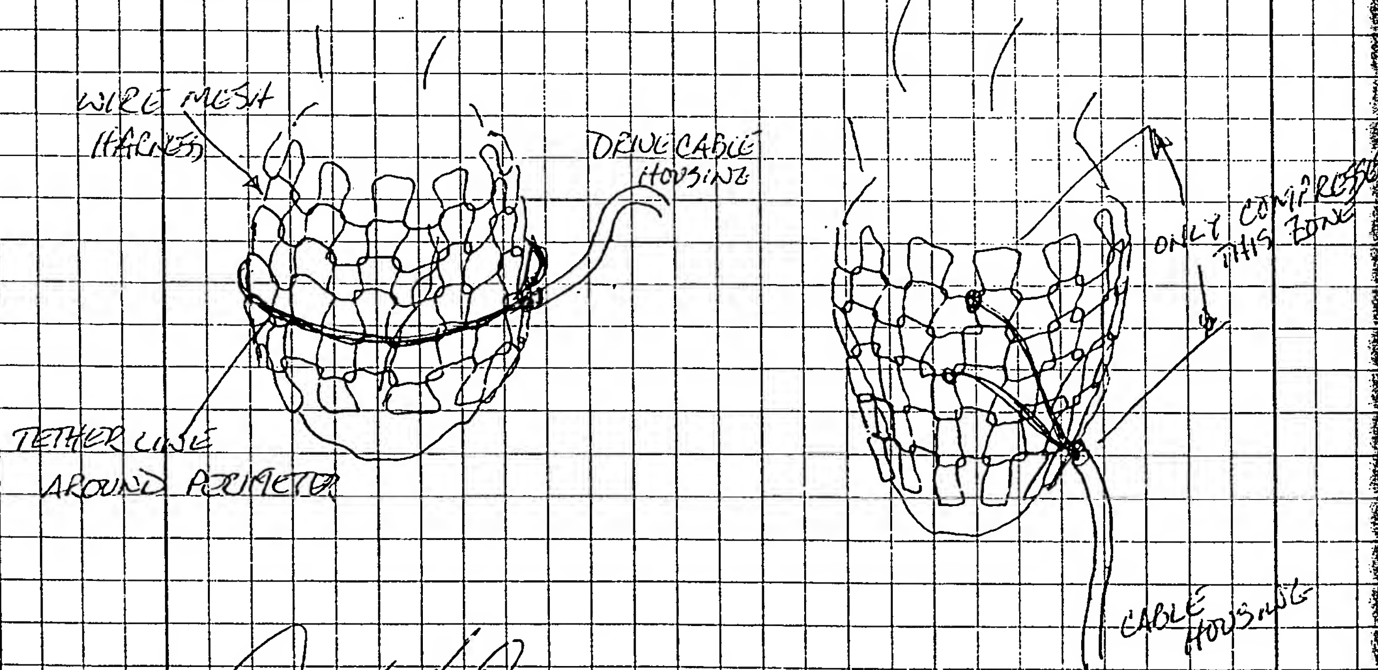
Figure 6: Low profile anchors fully inserted and partially inserted.

SOLDERED END LOW PROFILE ANCHOR IS MADE OF 302 STAINLESS STEEL WITH A NICKEL COATING. ANCHORS MAY BE ELECTROPOLISHED BEFORE CHRONIC ANIMAL STUDIES

2/23/00 READ + UNDERSTOOD 2/29/00

ACTIVELY DRIVEN WIRE MESH HARNESS

THE WIRE MESH HARNESS MAY BE COMPRESSED BY ADDING A TETHER LINE, OR CABLE AROUND THE CIRCUMFERENCE OF THE HARNESS, OR MAY BE ATTACHED TO A PORTION OF THE HARNESS TO PARTIALLY COMPRESS THE HARNESS. THIS PARTIAL COMPRESSION WOULD ALLOW TARGETING COMPRESSION TO SECTIONS OF THE HEART SUCH AS THE LEFT VENTRICLE.



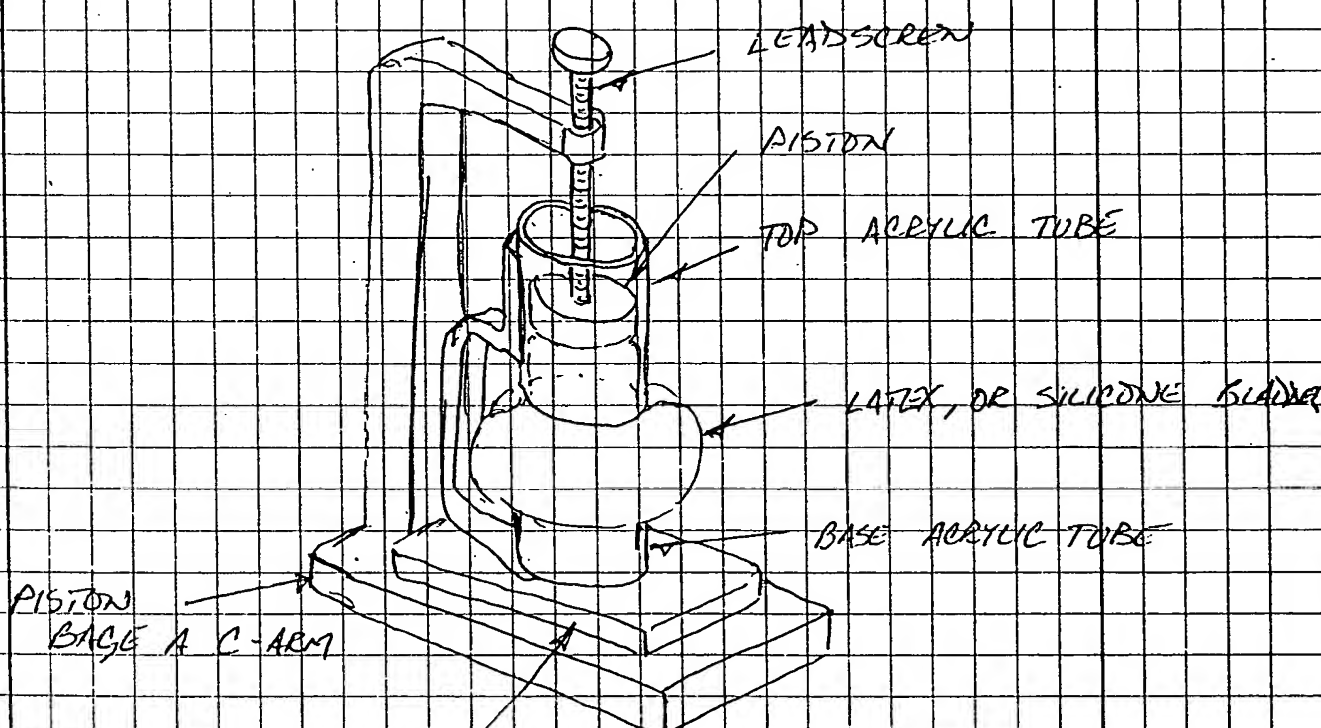
2-25-00

READ & UNDERSTOOD

3/29/00

PRESSURE VS. VOLUME TESTER

A TEST FIXTURE WILL BE NEEDED TO EVALUATE THE PRESSURE THE WIRE MESH HARNESS WILL EXERT ON THE HEART IN DIFFERENT CONFIGURATIONS AND DIFFERENT DIAMETERS. THE FIXTURE/TESTER SHOULD BE ABLE TO CHARACTERIZE DIAMETER CHANGE IN A BLADDER (WITH HARNESS) GIVEN A CHANGE IN VOLUME. PRESSURE AT GIVEN DIAMETERS WILL ALSO BE IMPORTANT.

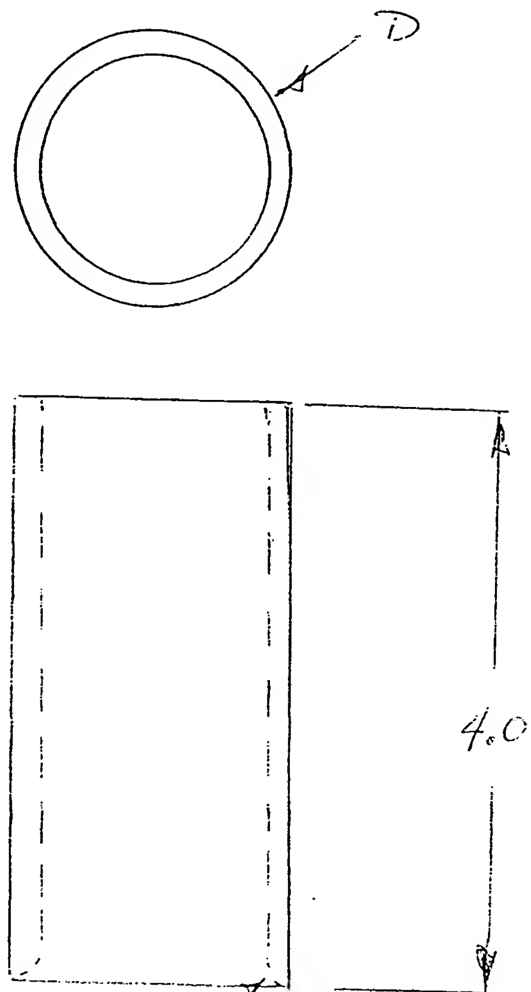


2-25-00

READ
+ UNDERSTOOD

3/29/00

PV TESTER COMPONENT PARTS



SMOOTH RADIUS (ONE END)

TOP TUBE

MATL: ACRYLIC (SUPPLIED)

TOL: .X = ± 0.1

1 EACH DIAMETER

2-25-00

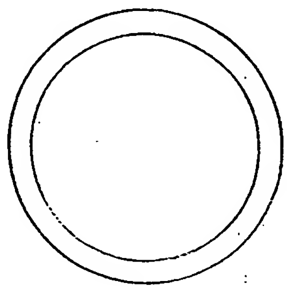
3-10-00

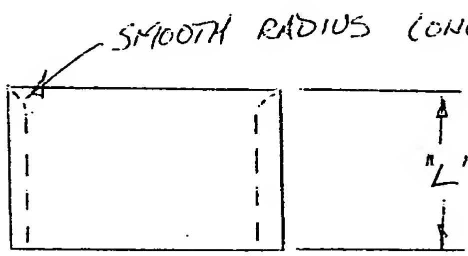
READ & UNDERSTOOD 3/29/00

PV TESTER COMPONENT PARTS

1.0

1.5





BASE TUBE

MATL: ACRYLIC (SUPPLIED)

TOL: .X = ± .1

1 EACH DIAMETER

2-25-00

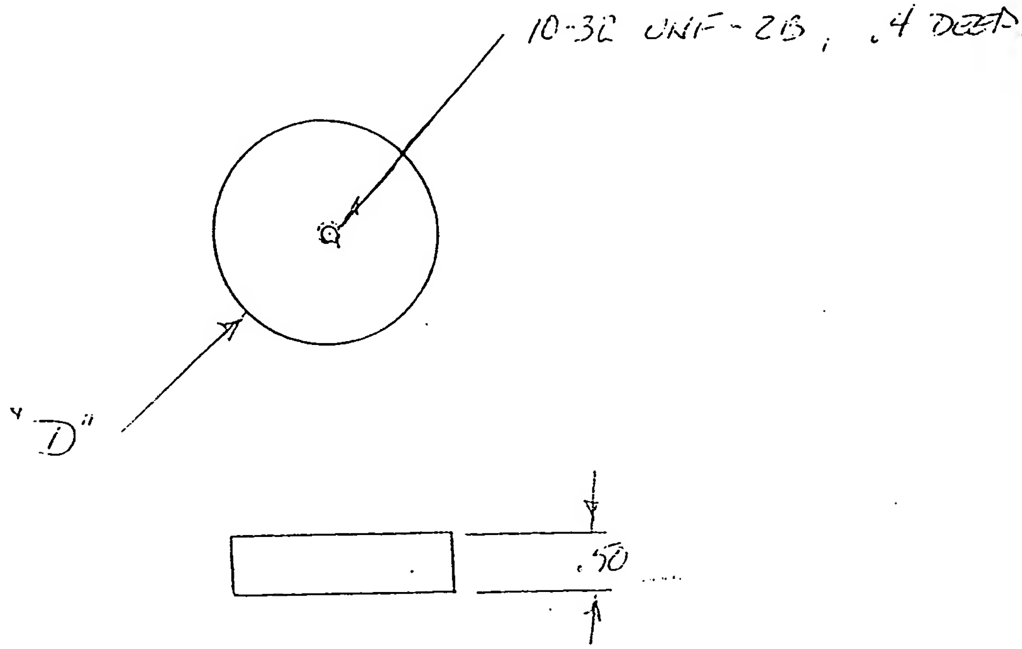
3/10/00

READ & UNDERSTOOD 3/24/00

AV TESTER PARTS

D_1 = .25" LESS THAN ACRYLIC TUBE I.D.

D_2 = SLIP FIT (.005-.010) WITH ACRYLIC TUBE I.D.



COMPRESSION PISTON

MATERIAL: ALUMINUM, DELRIN, ACRYLIC OR EQUIV

TOL. = XX = ± .01
XXX = ± .005

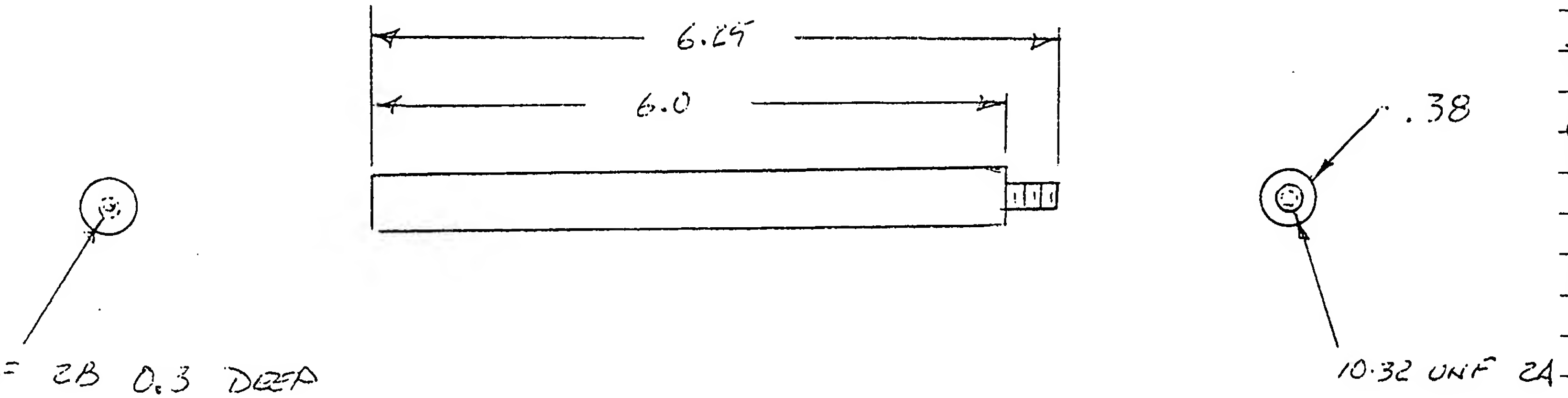
1 EACH PER ACRYLIC TUBE

2-25-00

3/10/00

READ + UNDERSTOOD 3/31/

PV TESTER PARTS



THREADED EXTENDER

MATERIAL: ALUMINUM

TOL.: X = ± .1
XX = ± .01

1 EACH

2-25-00

3/10/00

READ

3/29/00

PV/AD TESTER

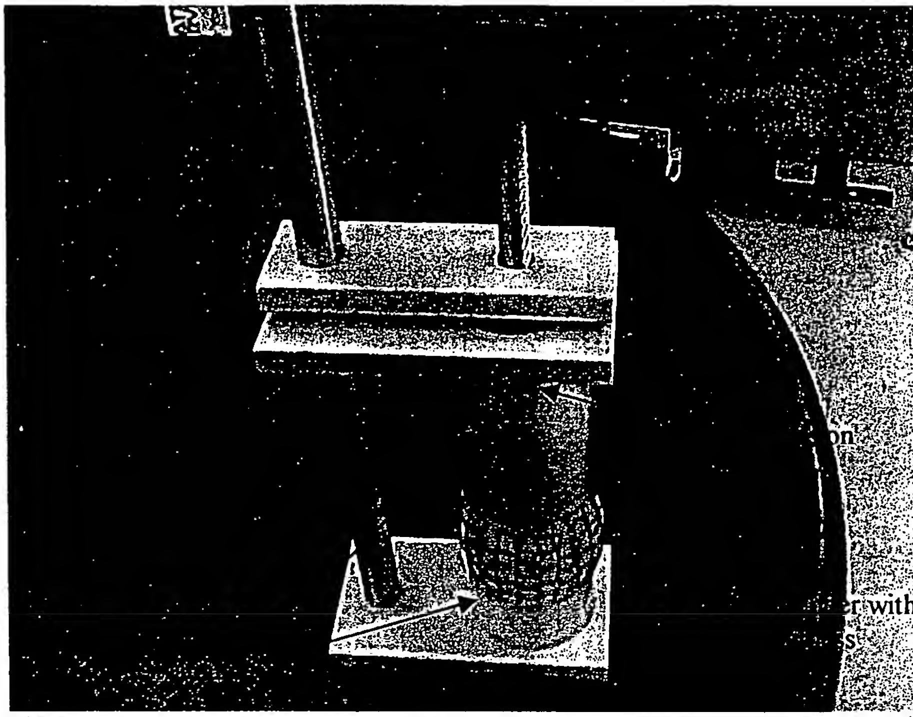


Figure 1: Harness characterization/test fixture.

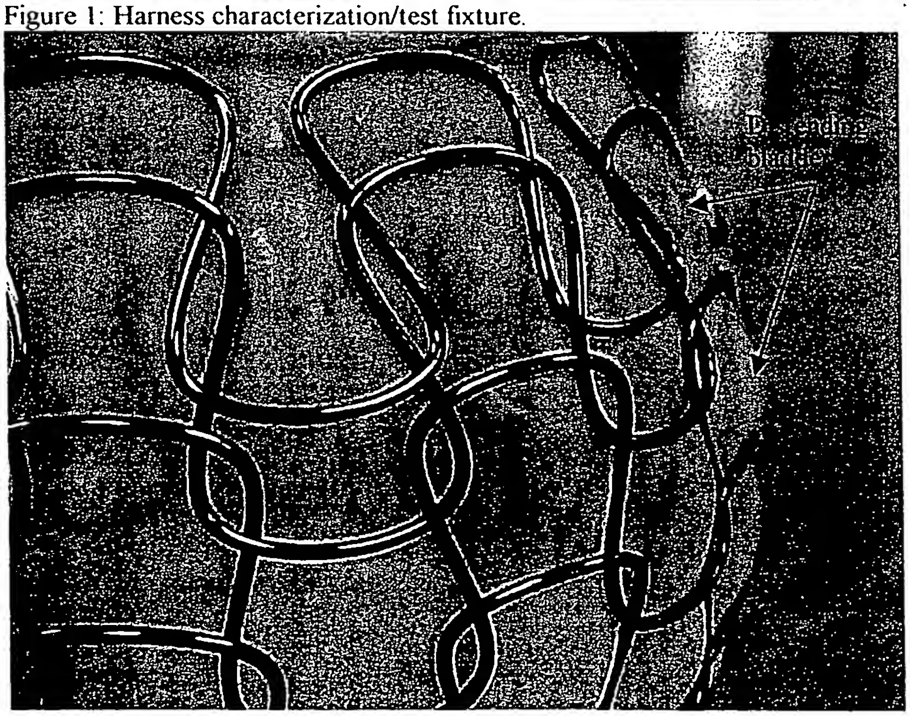


Figure 2: Bladder extruding out between struts at higher pressures (.032").

3/10/00

3/10/00

READ + UNDERSTOOD

3/29/00

PV/PD TESTER

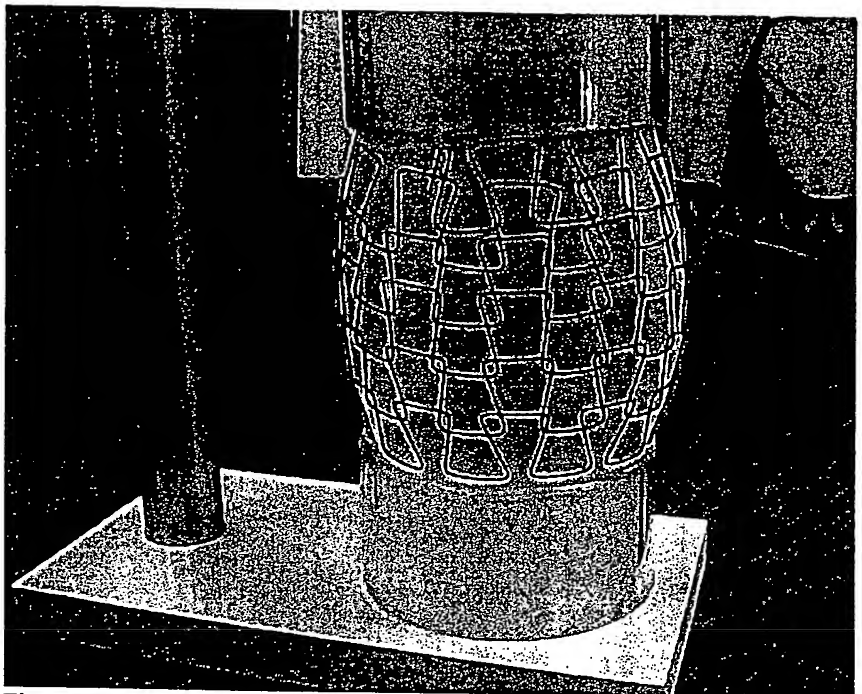


Figure 3: .015" harness slightly pressurized.

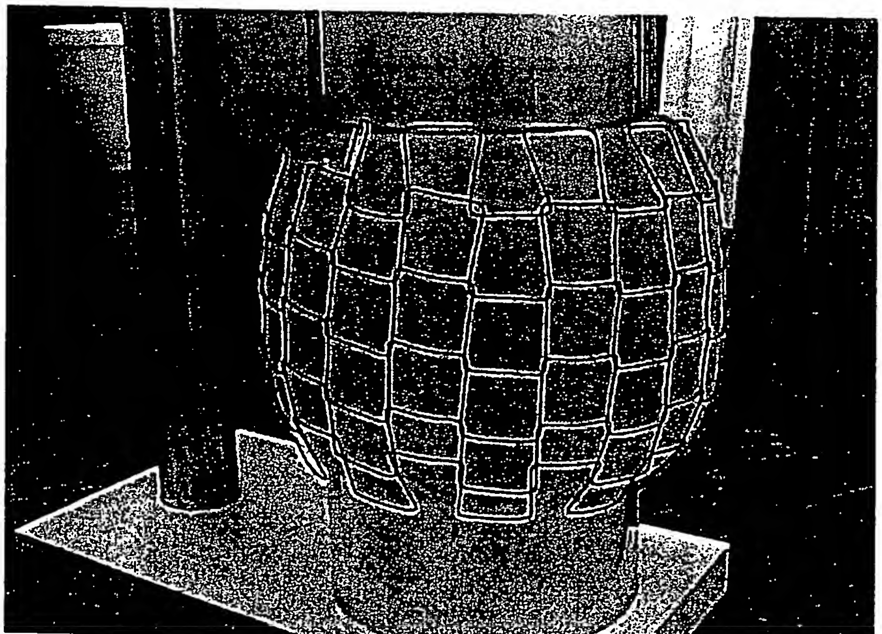


Figure 4: .015 harness extended (note struts at 90°).

3-10-00

READ + UNDERSTOOD

3/29/00

PV/PD TESTER

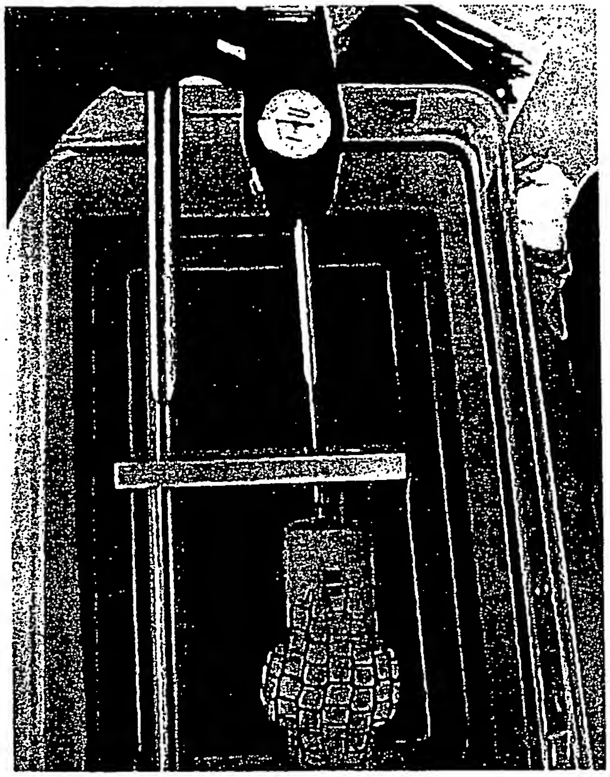


Figure 1: Tester using water in the bladder instead of air and submerged in water.

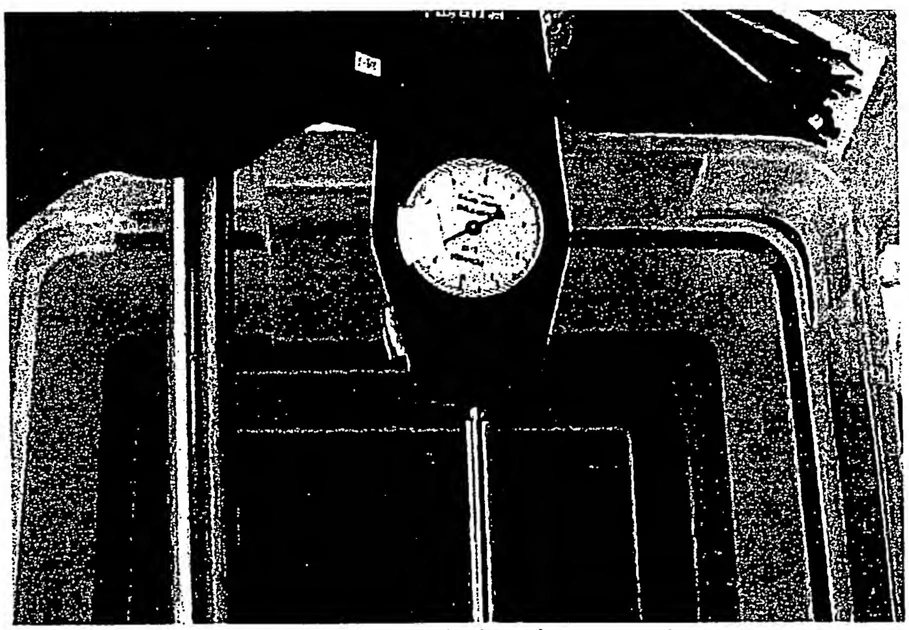


Figure 2: Ten pound force gauge attached to piston extender.

3/10/00

READ
& UNDERSTOOD

3/24/00

PV/PD TESTER

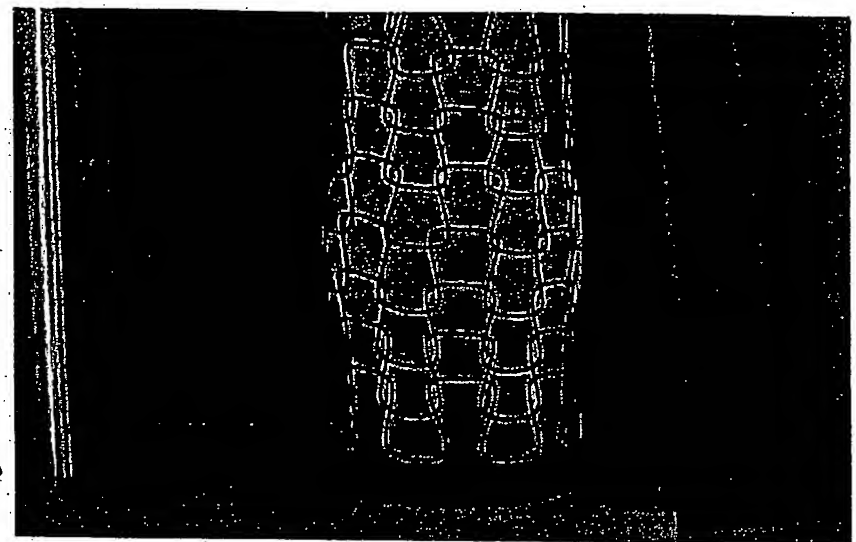


Figure 3: .015" harness with low pressure in bladder.

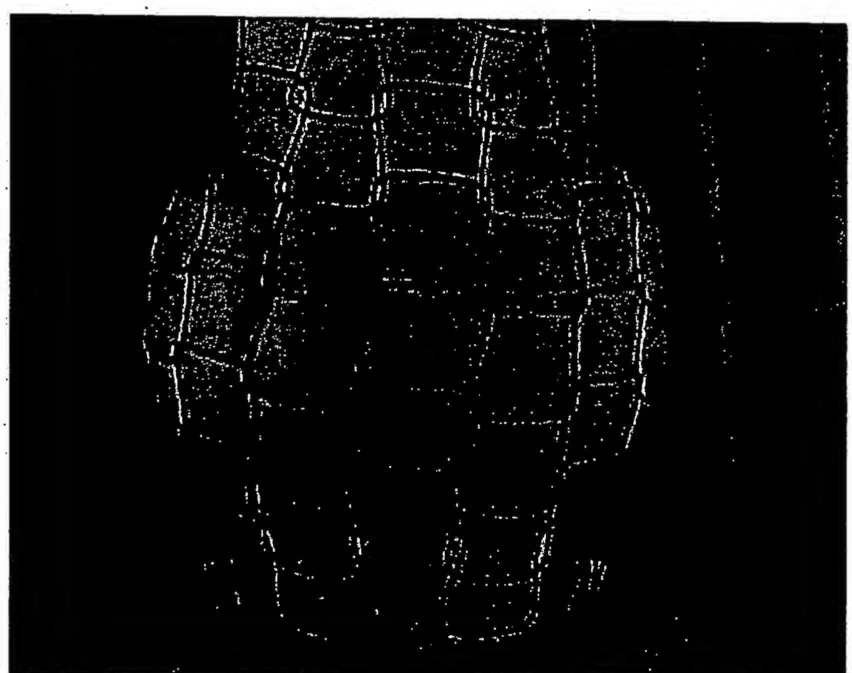


Figure 4: Harness extended, but restraining the bladder.

3/10/00

3/10/00

READ & UNDERSTOOD

3/29/00